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■

GRADING AND INSPECTION

General Specifications for Approved Dairy Plants and Standards for Grades of Dairy Products

Title 7—Agriculture

CHAPTER I—AGRICULTURAL MARKETING SERVICE (STANDARDS, INSPECTIONS, MARKETING PRACTICES), DEPARTMENT OF AGRICULTURE

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED DAIRY PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

Under authority contained in the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621), a notice of proposed rule making covering the revision of the General Specifications for Dairy Plants Approved for USDA, Inspection and Grading Service, hereinafter referred to as General Specifications, was published in the FEDERAL REGISTER of February 12, 1975 (40 FR 6608). The revision updates and upgrades the various requirements relative to technological changes that have occurred in equipment, facilities, and manufacturing operations since the General Specifications became effective May 16, 1967.

STATEMENT OF CONSIDERATIONS

Interested persons were given until July 1, 1975, to submit written data, views or arguments with respect to the proposed rulemaking. Twenty-one letters were received by the Hearing Clerk on the proposal. Two letters were from individuals, three from State agencies, ten from industry, and six from trade associations. Some of the commentors from industry are members of the trade associations who submitted comments. Four trade associations expressed favorable comments for adoption of the revised General Specifications and one individual expressed favorable comments for adoption of the abnormal milk program as proposed. Comments were as follows:

1. One commentor suggested clarification that the General Specifications apply only to human food plants. This intent is implied in the title of the document and its content. The high level requirements for plant and facilities, sanitation and product quality are consistent only with a human food operation.

2. One commentor questioned whether the definition of an approved plant was intended to prohibit the use of imported dairy products. USDA inspection services are provided under authority of the Agricultural Marketing Act of 1946. The Department interprets this act to apply to domestic products and not imports.

3. One commentor suggested an addition to the definition of an inspector to include licensed industry employees or consultants. Maintaining the integrity of the voluntary service requires inspectors who are not biased by any financial interest, loyalty or responsibility to applicants requesting service. The service must be provided fairly and uniformly on a national basis. It would be difficult and impractical for industry employees or consultants to meet these criteria.

4. One commentor suggested that the light intensity in the plant processing and packaging areas and the storage rooms be increased. The requirement for at least 30 foot candles in the processing and packaging areas and 5 foot candles in storage areas are minimum requirements. The light also shall be ample and well distributed. Experience has shown that the requirements are adequate.

5. Six commentors suggested deleting the listed requirements for disposal of dairy wastes and instead make requirements consistent with the Environmental Protection Agency. Such change was made.

6. One commentor suggested deleting the detailed description for general construction of equipment and utensils and substituting requirements for compliance with 3–A Sanitary Standards. To date, 3–A Sanitary Standards have not been developed for all equipment. Therefore, the detailed requirements are needed.

7. One commentor suggested that properly covered facilities with open sides should be sufficient for washing and sanitizing bulk tank trucks. The General Specifications permit such covered facilities where adverse climatic conditions are not encountered. However, plants located in areas where adverse climatic conditions may be encountered shall have enclosed facilities at the plant or available at a central location.

8. Two comments were received suggesting stricter requirements on use of antibiotics for treating mastitis infection in cows. One commentor suggested additional penalties for milk containing antibiotics. The other suggested more frequent testing for presence of antibiotics in milk. The proposed regulations are accepted procedures for surveillance on all grades of milk. Therefore, the Department accepts these procedures. Since States are responsible for laws regulating the quality of milk, an individual State may institute tighter regulations.

9. Four comments were received concerning the proposed abnormal milk program. One comment supports the program; one comment suggests raising the permitted somatic cell count from 1,500,000 to 2,000,000; one comment suggests reducing the regimen of testing; and one comment suggests a provision to permit each laboratory to set its own level above which confirmatory testing using the Wisconsin Mastitis Test is to be done. Accordingly, a provision was included in the specifications for each laboratory to establish its own Wisconsin Mastitis Test score above which confirmatory testing is to be done. This change makes the specifications consistent with those of the National Mastitis Council and the Abnormal Milk Committee of the National Conference on Interstate Milk Shipments. The Department's position is that abnormal milk should be excluded from all grades of milk and supports the efforts of the dairy industry and regulatory agencies for a strong and uniform program.

10. Two commentors suggested deletion of the requirement for the sediment test on producer milk because it is an unnecessary test having no public health significance. The Department finds that the test does serve a useful purpose in the production of all grades of milk. The test provides the producer with a visual test result which can be used in making corrections to assure the production of clean milk. The deletion of the sediment test requirement would eliminate the incentive for a careless producer to give proper attention to production of clean milk.

11. Two commentors suggested changes in the bacterial estimate classification for milk from producers. Both commentors suggested reducing the probationary period for undergrade milk and one questioned the correlation between the Resazurin test time and a 500,000 per ml. count. One commentor's additional remarks were relative to Grade A and not manufacturing grade milk. The Department feels the probationary period of four weeks with required weekly testing is practical and restrictive since failure to comply eliminates the producer from any market. No correlation between resazurin test and a 500,000 per ml. count is intended. The individual tests are bacterial estimates and the resazurin test does serve a useful purpose for quality improvement for manufacturing grade milk.

12. Two commentors suggested changing the requirement for age of milk when delivered to the plant from not more than two to not more than three days. With modern methods of farm bulk tanks and transport tankers milk is held at a constant cold temperature which adequately protects the quality. The suggested change was made.

13. Seven commentors suggested changing the bacterial requirement that commingled milk "shall" not exceed three million to "should" not exceed three million. The Department's Requirements for Milk for Manufacturing Purposes Recommended for State Adoption includes the requirement that commingled milk shall not exceed three million bacterial count. Many States have adopted these requirements as laws or regulations and are enforcing them. The Department should do no less than support this requirement in its inspection and grading program offered to plants on a voluntary basis.

14. Six commentors suggested that all product definitions be the same as those established by the Food and Drug Administration (FDA). The FDA identity standards are applicable to all products as suggested. However, the Department has additional requirements for products as may be required for assignment of a U.S. grade. Therefore, some product definitions are more restrictive. However, products not meeting the more restrictive requirements may be inspected and certificates issued on the basis of buyer's or seller's specifications.

15. One commentor suggested that the requirement that high pressure pumps shall comply with the 3–A Sanitary Standards for Homogenizers and Pumps of the Plunger Type be applicable to new installations only. Old style high pressure pumps not complying with the 3–A Standards are difficult to clean and are a potential source of bacterial contamination. The Department contends that sufficient time has been allowed for replacement of this equipment and because of its potential for contamination of product old style high pressure pumps should no longer be acceptable.

16. Two commentors objected to the capacity of bulk bins being limited as directed by the Administrator. The specifications were changed to reflect the intent of the statement which is to provide proper operating practices.

17. Four commentors recommended the oxygen requirement of not more than 2.0 percent for consumer packages of dry whole milk bearing USDA official grade identification be changed to not more than 3.0 percent. The reduction of oxygen content by replacement with an inert gas helps prevent development of oxidized flavor in the milk thus extending shelf life. Available information shows that to maintain quality for a satisfactory shelf life of the product the lower oxygen content is necessary. Therefore, the Department is retaining the requirement at not more than 2.0 percent oxygen in product packed with USDA official identification.

18. One commentor recommended deletion of the requirement for frequency of shipment of milkfat from whey from cheese plants. The Department's experience has shown that more attention is needed in the handling of this product. A limit on age of product when shipped should improve the quality and stability of the product.

19. Four commentors objected to the requirements that the nonfat dry milk used in

making cottage cheese meet the requirements for U.S. Extra Grade, the U.S. Low Heat Classification, the direct microscopic count not exceeding 75 million per gram, and be not more than 6 months old when used. These requirements were moved to the applicable section for product packaged with USDA official identification and appropriate requirements inserted in Section 58.519(b). Nonfat dry milk meeting the U.S. Low Heat Classification is retained as a "should" requirement since it contributes to a more desirable quality cottage cheese.

20. Two commentors objected to listing physical requirements for cottage cheese packaged with USDA official identification. It is the usual practice to use U.S. grade standards as a basis for requirements for products packaged with USDA official identification. Since there are no U.S. grade standards established for cottage cheese it was necessary to establish requirements for the product.

21. One commentor objected to the requirement for a temperature recording device on process cheese cookers since the temperatures used are in excess of those required for pasteurization. The name of the product "Pasteurized Process Cheese," indicates pasteurization. To assure pasteurization in any food product a record of the pasteurization time and temperature is essential. Therefore, the requirement is retained.

22. Six commentors recommended deletion of lactose from coverage by the proposed revision of the General Specifications because they contend it is a carbohydrate and not a dairy product. The Department recognizes the uniqueness of lactose in that it is derived from whey, a by-product of cheese making, and that it should be treated as other nutritive sweeteners. This recommendation has been accepted recognizing lactose to be a food product, and provision has been made for processing and handling in accordance with good manufacturing practices required for similar products. It is necessary to cover lactose in these regulations since its processing and handling are an integral part of dairy plant operations in certain plants that use the voluntary inspection services provided by the Department.

23. Four commentors recommended deletion of the medium acid classification for dry whey and one commentor favored retention of the classification suggesting the term "semi-sweet whey" for this product. The majority of commentors contend that the establishment of a name for the third category for dry whey is unnecessary and would create confusion in marketing. The Department accepts this recommendation and the suggestion that dry whey with titratable acidity between sweet and acid categories be identified as "Dry Whey —— percent Titratable Acidity." The four commentors further recommended a maximum 0.16 percent titratable acidity for dry sweet whey and a minimum of 0.30 percent for dry acid whey. The one commentor recommended a maximum of 0.20 percent for dry sweet whey and a minimum of 0.35 percent for dry acid whey. The minimum titratable acidity for dry acid whey was changed from 0.40 percent in the proposed revision to 0.35 percent to more accurately describe this category of dry whey. The maximum 0.16 percent titratable acidity for dry sweet whey was retained since this acidity has been long established for dry sweet whey.

24. Two commentors recommended lowering from 40 percent to 28 or 30 percent the required total solids content for condensed whey, when such whey is transported to another plant for further processing without requiring repasteurization. The long established requirement for 40 percent total solids in condensed whey when transported to another plant for use without repasteurization has provided public health protection and prevented product quality deterioration. No data was provided to assure the same health and quality protection with the lower total solids. Therefore, the Department has no basis for change.

25. Eight commentors suggested various changes in the supplement covering whey, whey products and lactose. The comments concerned product definitions, equipment and utensils, and operating procedures. The Department considered these comments in rewriting the supplement. The revision embodies sound dairy manufacturing principles for the production of whey and whey products but allows processing flexibility where necessary for technological reasons.

26. Five commentors recommended the inclusion of lactose as a permissible sugar in sweetened condensed milk. The Department accepts this recommendation based on the Food and Drug Administration identity standards for sweetened condensed milk, which provide for the use of suitable nutritive sweeteners.

27. One commentor questioned the Department's intent of defining and including ultra-pasteurized products in the supplement covering evaporated, condensed or ultra-pasteurized products. Ultra-pasteurized is defined as a specific process and is not intended as a classification for dairy products. Fluid milk products have been deleted from these General Specifications and the term dairy products as used herein is defined under definitions.

28. One commentor recommended the inclusion of a test for added water as a requirement for quality and wholesomeness of milk. The General Specifications specify that the Federal Food, Drug and Cosmetic Act shall be complied with. Milk with added water is considered adulterated. Since each State has the regulatory responsibility for assuring that only legal milk is marketed, the Department feels the problem is adequately regulated.

29. A number of commentors suggested editorial changes to improve the clarity or intent of the General Specifications. Also, they questioned the use of certain examples and descriptive detail. Deletions were suggested where other government agencies have regulatory responsibility. Many of these suggestions were helpful to improve clarity or intent of the General Specifications. A number of other suggestions for minor changes which updated references, technological improvements or established practices were acceptable to the Department and changes were made accordingly.

30. One commentor objected to the provision in the definition of dry whey that no ingredients may be added for the purpose of altering the natural acidity. Because of the shortage of rennet, microbial enzymes have been substituted in the manufacture of certain cheeses. The commentor contends that higher heat treatment is required to inactivate microbial enzymes than rennet unless the acidity is lowered by the addition of an acceptable alkali. In addition, the commentor claimed that an active enzyme in dry whey would be objectionable in some uses and the higher heat treatment would tend to denature some of the protein in the product. The Department finds that the problem is limited to enzymes made from specific microbial strains. Other microbial enzymes which are widely accepted and do not have the specific limitation are readily available. Therefore, the Department cannot justify the suggested change.

After consideration of the written comments filed with respect to the notice of proposed rule making and other information available, 7 CFR Part 58, Subpart B is revised as set forth below:

SUBPART B—GENERAL SPECIFICATIONS FOR DAIRY PLANTS APPROVED FOR USDA INSPECTION AND GRADING SERVICE[1]

DEFINITIONS

Sec.
58.101 Meaning of words.

PURPOSE

58.122 Approved plants under USDA inspection and grading service.

APPROVED PLANTS

58.123 Survey and approval.
58.124 Denial or suspension of plant approval.

PREMISES, BUILDINGS, FACILITIES, EQUIPMENT AND UTENSILS

58.125 Premises.
58.126 Buildings.
58.127 Facilities.
58.128 Equipment and utensils.

PERSONNEL, CLEANLINESS AND HEALTH

58.129 Cleanliness.
58.130 Health.

PROTECTION AND TRANSPORT OF RAW MILK AND CREAM

58.131 Equipment and facilities.

QUALITY SPECIFICATIONS FOR RAW MILK

58.132 Basis for classification.
58.133 Methods for quality and wholesomeness determination.
58.134 Sediment content.
58.135 Bacterial estimate.
58.136 Rejected milk.
58.137 Excluded milk.
58.138 Quality testing of milk from new producers.
58.139 Record of tests.
58.140 Field service.
58.141 Alternate quality control program.

OPERATIONS AND OPERATING PROCEDURES

58.142 Product quality and stability.
58.143 Raw product storage.
58.144 Pasteurization or Ultra-Pasteurization.
58.145 Composition and wholesomeness.
58.146 Cleaning and sanitizing treatment.
58.147 Insect and rodent control program.
58.148 Plant records.
58.149 Alternate quality control programs for dairy products.

PACKAGING AND GENERAL IDENTIFICATION

58.150 Containers.
58.151 Packaging and repackaging.
58.152 General identification.

STORAGE OF FINISHED PRODUCT

58.153 Dry storage.
58.154 Refrigerated storage.

INSPECTION, GRADING AND OFFICIAL IDENTIFICATION

58.155 Grading.
58.156 Inspection.
58.157 Inspection or grading certificates.
58.158 Official identification.

EXPLANATION OF TERMS

58.159 Terms.

[1] Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, Environmental Protection Act, or applicable laws and regulations of any State or Municipality.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING NONFAT DRY MILK, INSTANT NONFAT DRY MILK, DRY WHOLE MILK, AND DRY BUTTERMILK

DEFINITIONS

Sec.
58.205 Meaning of words.

ROOMS AND COMPARTMENTS

58.210 Dry storage of product.
58.211 Packaging room for bulk products.
58.212 Hopper or dump room.
58.213 Repackaging room.

EQUIPMENT AND UTENSILS

28.214 General construction, repair and installation.
58.215 Pre-heaters.
58.216 Hotwells.
58.217 Evaporators and/or vacuum pans.
58.218 Surge tanks.
58.219 High pressure pumps and lines.
58.220 Drying systems.
58.221 Collectors and conveyors.
58.222 Dry dairy product cooling equipment.
58.223 Special treatment equipment.
58.224 Sifters.
58.225 Clothing and shoe covers.
58.226 Portable and stationary bulk bins.
58.227 Sampling device.
58.228 Dump-hoppers, screens, mixers and conveyors.
58.229 Filler and packaging equipment.
58.230 Heavy duty vacuum cleaners.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

58.231 General.
58.232 Milk.
58.233 Skim milk.
58.234 Buttermilk.
58.235 Modified dry milk products.

OPERATIONS AND OPERATING PROCEDURES

58.236 Pasteurization and heat treatment.
58.237 Condensed surge supply.
58.238 Condensed storage tanks.
58.239 Drying.
58.240 Cooling dry products.
58.241 Packaging, repackaging and storage.
58.242 Product adulteration.
58.243 Checking quality.
58.244 Number of samples.
58.245 Method of official sample analysis.
58.246 Cleaning of dryers, collectors, conveyor ducts, sifters and storage bins.
58.247 Insect and rodent control program.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.248 Nonfat dry milk.
58.249 Instant nonfat dry milk.
58.250 Dry whole milk.
58.251 Dry buttermilk.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING BUTTER AND RELATED PRODUCTS

DEFINITIONS

58.305 Meaning of words.

ROOMS AND COMPARTMENTS

58.311 Coolers and freezers.
58.312 Churn rooms.
58.313 Print and bulk packaging rooms.

EQUIPMENT AND UTENSILS

58.314 General construction, repair, and installation.
58.315 Continuous churns.
58.316 Conventional churns.
58.317 Bulk butter trucks, boats, texturizers, and packers.
58.318 Butter, frozen or plastic cream melting machines.
58.319 Printing equipment.
58.320 Brine tanks.
58.321 Cream storage tanks.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.322 Cream.
58.323 Whipped butter.
58.324 Butteroil.
58.325 Anhydrous milkfat.
58.326 Plastic cream.
58.327 Frozen cream.
58.328 Salt.
58.329 Color.
58.330 Butter starter cultures.
58.331 Starter distillates.

OPERATIONS AND OPERATING PROCEDURES

58.332 Segregation of raw material.
58.334 Pasteurization.
58.335 Quality control tests.
58.336 Frequency of sampling for quality control of cream, butter and related products.
58.337 Official test methods.
58.338 Composition and wholesomeness.
58.339 Containers.
58.340 Printing and packaging.
58.341 Repackaging.
58.342 General identification.
58.343 Storage of finished product in coolers.
58.344 Storage of finished product in freezer.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.345 Butter.
58.346 Whipped butter.
58.347 Butteroil or anhydrous milkfat.
58.348 Plastic cream.
58.349 Frozen cream.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

DEFINITIONS

58.405 Meaning of words.

ROOMS AND COMPARTMENTS

58.406 Starter facility.
58.407 Make room.
58.408 Brine room.
58.409 Drying room.
58.410 Paraffining room.
58.411 Rindless cheese wrapping area.
58.412 Coolers or curing rooms.
58.413 Cutting and packaging rooms.

EQUIPMENT AND UTENSILS

58.414 General construction, repair and installation.
58.415 Starter vats.
58.416 Cheese vats, tanks, and drain tables.
58.417 Mechanical agitators.
58.418 Automatic cheese making equipment.
58.419 Curd mill and miscellaneous equipment.
58.420 Hoops, forms and followers.
58.421 Press.
58.422 Brine tank.
58.423 Cheese vacuumizing chamber.
58.424 Monorail.
58.425 Conveyor for moving and draining block or barrel cheese.
58.426 Rindless cheese wrapping equipment.
58.427 Paraffin tanks.
58.428 Specialty equipment.
58.429 Washing machine.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.430 Milk.
58.431 Hydrogen peroxide.
58.432 Catalase.
58.433 Cheese cultures.
58.434 Calcium chloride.
58.435 Color.
58.436 Rennet, pepsin, or other milk clotting enzymes and flavor enzymes.
58.437 Salt.

OPERATION AND OPERATING PROCEDURES

58.438 Cheese from pasteurized milk.
58.439 Cheese from unpasteurized milk.
58.440 Make schedule.
58.441 Records.
58.442 Laboratory and quality control tests.
58.443 Whey handling.
58.444 Packaging and repackaging.
58.445 General identification.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.446 Quality requirements.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING COTTAGE CHEESE

DEFINITIONS

58.505 Meaning of words.

ROOMS AND COMPARTMENTS

58.510 Rooms and compartments.

EQUIPMENT AND UTENSILS

58.511 General construction, repair and installation.
58.512 Cheese vats or tanks.
58.513 Agitators.
58.514 Container fillers.
58.515 Mixers.
58.516 Starter vats.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.517 General.
58.518 Milk.
58.519 Dairy products.
58.520 Non dairy ingredients.

OPERATIONS AND OPERATING PROCEDURES

58.521 Pasteurization and product flow.
58.522 Reconstituting nonfat dry milk.
58.523 Laboratory and quality control tests.
58.524 Packaging and general identification.
58.525 Storage of finished product.

REQUIREMENTS FOR COTTAGE CHEESE BEARING USDA OFFICIAL IDENTIFICATION

58.526 Official identification.
58.527 Physical requirements.
58.528 Microbiological requirements.
58.529 Chemical requirements.
58.530 Keeping quality requirements.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING FROZEN DESSERTS

DEFINITIONS

58.605 Meaning of words.

ROOMS AND COMPARTMENTS

58.619 Mix processing room.
58.620 Freezing and packaging rooms.
58.621 Freezing tunnels.
58.622 Hardening and storage rooms.

EQUIPMENT AND UTENSILS

58.623 Homogenizer.
58.624 Freezers.
58.625 Fruit or syrup feeders.
58.626 Packaging equipment.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.627 Milk and dairy products.
58.628 Sweetening agents.
58.629 Flavoring agents.
58.630 Stabilizers.
58.631 Emulsifiers.
58.632 Acid.
58.633 Color.

OPERATIONS AND OPERATING PROCEDURES

Sec.
58.634 Assembling and combining mix ingredients.
58.635 Pasteurization of the mix.
58.636 Homogenization.
58.637 Cooling the mix.
58.638 Freezing the mix.
58.639 Addition of flavor.
58.640 Packaging.
58.641 Hardening and storage.
58.642 Quality control tests.
58.643 Frequency of sampling.
58.644 Test methods.
58.645 General identification.
58.646 Official identification.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.647 Composition requirements for ice cream.
58.648 Microbiological requirements for ice cream.
58.649 Physical requirements for ice cream.
58.650 Requirements for frozen custard.
58.651 Requirements for ice milk.
58.652 Composition requirements for sherbet.
58.653 Microbiological requirements for sherbet.
58.654 Physical requirements for sherbet.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING PROCESSING AND PACKAGING PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS

DEFINITIONS

58.705 Meaning of Words.

EQUIPMENT AND UTENSILS

58.706 General construction, repair and installation.
58.707 Conveyors.
58.708 Grinders or shredders.
58.709 Cookers.
58.710 Fillers.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.711 Cheddar, colby, washed or soaked curd, granular or stirred curd cheese.
58.712 Swiss.
58.713 Gruyere.
58.714 Cream cheese, Neufchatel cheese.
58.715 Cream, plastic cream, and anhydrous milkfat.
58.716 Nonfat dry milk.
58.717 Whey.
58.718 Flavor ingredients.
58.719 Coloring.
58.720 Acidifying agents.
58.721 Salt.
58.722 Emulsifying agents.

OPERATION AND OPERATING PROCEDURES

58.723 Basis for selecting cheese for processing.
58.724 Blending.
58.725 Trimming and cleaning.
58.726 Cutting and grinding.
58.727 Adding optional ingredients.
58.728 Cooking the batch.
58.729 Forming containers.
58.730 Filling containers.
58.731 Closing and sealing containers.
58.732 Cooling the packaged cheese.
58.733 Quality control tests.

REQUIREMENTS FOR PROCESSED CHEESE PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.734 Official identification.
58.735 Quality specifications for raw materials.
58.736 Pasteurized process cheese.
58.737 Pasteurized process cheese food.
58.738 Pasteurized process cheese spread and related products.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING WHEY, WHEY PRODUCTS AND LACTOSE

DEFINITIONS

Sec.
58.805 Meaning of words.

ROOMS AND COMPARTMENTS

58.806 General.

EQUIPMENT AND UTENSILS

58.807 General construction, repair and installation.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.808 Whey.

OPERATIONS AND OPERATING PROCEDURES

58.809 Pasteurization.
58.810 Temperature requirements.
58.811 General.
58.812 Methods of official sample analysis.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.813 Dry whey.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING EVAPORATED, AND CONDENSED MILK OR ULTRA-PASTEURIZED DAIRY PRODUCTS

DEFINITIONS

58.905 Meaning of words.

EQUIPENT AND UTENSILS

58.912 General construction, repair and installation.
58.913 Evaporators and vacuum pans.
58.914 Fillers.
58.915 Batch or continuous in-container thermal processing equipment.
58.916 Homogenizer.

OPERATIONS AND OPERATING PROCEDURES

58.917 General.
58.918 Standardization.
58.919 Pre-heat, pasteurization.
58.920 Homogenization.
58.921 Concentration.
58.922 Thermal processing.
58.923 Filling containers.
58.924 Aseptic filling.
58.925 Sweetened condensed.
58.926 Heat stability.
58.927 Storage.
58.928 Quality control tests.
58.929 Frequency of sampling for quality control.
58.930 Official test methods.
58.931 General identification.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

58.932 Milk.
58.933 Stabilizers.
58.934 Sugars.
58.935 Chocolate and cocoa.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.936 Milk.
58.937 Physical requirements for evaporated milk.
58.938 Physical requirements and microbiological limits for sweetened condensed milk.

Subpart B—Several Specifications for Dairy Plants Approved for USDA Inspection and Grading Service.

DEFINITIONS

§ 58.101 Meaning of words.

For the purpose of the regulations of this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Act.* The applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; (7 U.S.C. 1621–1627)), or any other Act of Congress conferring like authority.

(b) *Administrator.* The Administrator of the Agricultural Marketing Service or any other officer or employee of the Agricultural Marketing Service of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

(c) *Approved laboratory.* A laboratory in which the facilities and equipment used for official testing have been approved by the Administrator as being adequate to perform the necessary official tests in accordance with this part, and operates under a USDA surveillance program as set forth by the Administrator.

(d) *Approved plant.* One or more adjacent buildings, or parts thereof, comprising a single plant at one location in which the facilities and methods of operation therein have been surveyed and approved by the Administrator as suitable and adequate for inspection or grading service in accordance with the following:

(1) Shall satisfactorily meet the specifications of this subpart as determined by the Administrator.

(2) Receive dairy products only from plants, transfer stations, receiving stations and cream buying stations which satisfactorily comply with the applicable requirements of this subpart as determined by the Administrator. (Occasional shipments may be received from non-approved plants provided the product is tested and meets the quality requirements for No. 2 milk.)

(e) *Sanitizing treatment.* Subjection of a clean product contact surface to steam, hot water, hot air, or an acceptable sanitizing solution of sufficient strength, and for a duration of time to effectively destroy microorganisms. Sanitizing solutions shall comply with 21 CFR 121.2547.

(f) *Resident service.* Inspection or grading service performed at a dairy manufacturing plant or grading station by an inspector or grader assigned to the plant or station on a continuous basis.

(g) *Dairy products.* Butter, cheese (whether natural or processed), skim milk, cream, whey or buttermilk (whether dry, evaporated, stabilized or condensed), frozen desserts and any other food product which is prepared or manufactured in whole or in part from any of the aforesaid products, as the Administrator may hereafter designate.

(h) *Grader.* Any employee of the Department authorized by the Administrator or any other person to whom a license has been issued by the Administrator to investigate and certify, in accordance with the Act and this part, to shippers of products and other interested parties, the class, quality, quantity, and condition of such products.

(i) *Inspector.* Any employee of the Department authorized by the Administrator or any other person to whom a license has been issued by the Admin-

istrator to inspect and certify quality, quantity and condition of products, observe the manufacturing, processing, packaging and handling of dairy products, and to perform dairy plant surveys in accordance with the regulations of this part.

(j) *Inspection or grading service.* Means in accordance with this part, the act of (1) drawing samples of any product; (2) determining the class, grade, quality, composition, size, quantity, condition, or wholesomeness of any product by examining each unit or representative samples; (3) determining condition of product containers; (4) identifying any product or packaging material by means of official identification; (5) regrading or appeal grading of a previously graded product; (6) inspecting dairy plant facilities, equipment, and operations; such as, processing, manufacturing, packaging, repackaging, and quality control; (7) supervision of packaging inspected or graded product; (8) reinspection or appeal inspection; and (9) issuing an inspection or grading certificate or sampling, inspection, or other report related to any of the foregoing.

(k) *Milk.* The whole lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows located in modified accredited areas and modified certified areas or from cows in herds fully accredited as tuberculosis-free and certified brucellosis-free by the United States Department of Agriculture or in the process of being accredited.

(l) *Official identification.* Official identification is provided for use on product packed under USDA inspection. Any package label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe, and such official identification shall be of such form and contain such information as the Administrator may require.

(m) *Official methods.* Official Methods of Analysis of the Association of Official Analytical Chemists, a publication of the Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(n) *Pasteurization (Pasteurized).* Pasteurization shall mean that every particle of product shall have been heated in properly operated equipment to one of the temperatures specified in the table and held continuously at or above that temperature for at least the specified time (or other time/temperature relationship equivalent thereto in microbial destruction):

FLUID PRODUCTS

Temperature:	Time
145° F (vat pasteurization).	30 minutes.
161° F (high temperature short time pasteurization).	15 seconds.
191° F (higher heat shorter time pasteurization).	1.0 second.
194° F (higher heat shorter time pasteurization).	0.5 second.
201° F (higher heat shorter time pasteurization).	0.1 second.
204° F (higher heat shorter time pasteurization).	.05 second.
212° F (higher heat shorter time pasteurization).	.01 second.

PRODUCTS HAVING DAIRY INGREDIENTS WITH A FAT CONTENT OF 10 PERCENT OR MORE, OR CONTAIN ADDED SWEETENERS

150° F	30 minutes.
166° F	15 seconds.

FROZEN DESSERT MIX

155° F	30 minutes.
175° F	25 seconds.

CONDENSED MILK TO BE REPASTEURIZED

166° F	15 seconds.

(o) *Plant survey.* An appraisal of a plant to determine the extent to which facilities, equipment, method of operation, and raw material being received are in accordance with the provisions of this part. The survey shall be used to determine suitability of the plant for USDA inspection or grading service.

(p) *Plant status.* The extent to which a plant complies with this subpart shall be determined under procedures as set forth by the Administrator.

(q) *Producer.* The person or persons who exercise control over the production of the milk delivered to a processing plant or receiving station and who receive payment for this product.

(r) *Quality control.* The inspection of the quality of the raw material and the conditions relative to the preparation of the product from its raw state through each step in the entire process. It includes the inspection of conditions under which the product is prepared, processed, manufactured, packed and stored. In addition, assistance and guidance is offered to improve the raw milk quality, processing methods, quality, stability, and packaging and handling of the finished product.

(s) *Regulations.* The term "regulations" means the provisions contained in this part.

(t) *Shall.* Expresses a provision that is mandatory.

(u) *Should.* Expresses recommended nonmandatory provisions which when followed would significantly aid in a quality improvement program.

(v) *Standard methods.* Standard Methods for the Examination of Dairy Products, a publication of the American Public Health Association, 1790 Broadway, New York, New York.

(w) *3–A Sanitary Standards and Accepted Practice.* The latest standards for dairy equipment and accepted practices formulated by the 3–A Sanitary Standards Committees representing the International Association of Milk, Food and Environmental Sanitarians, the Food and Drug Administration and the Dairy Industry Committee. Published by the International Association of Milk, Food and Environmental Sanitarians, Box 701, Ames, Iowa.

(x) *"USDA" or "Department".* Means the United States Department of Agriculture.

(y) *Receiving Station.* Any place, premise, or establishment where milk or dairy products are received, collected or handled for transfer to a processing or manufacturing plant.

(z) *Transfer station.* Any place, premise, or establishment where milk or dairy products are transferred directly from one transport tank to another.

(aa) *Corrorison-resistant.* Those materials that maintain their original surface characteristics under prolonged influence of the product to be contacted, cleaning compounds and sanitizing solutions, and other conditions of the environment in which used.

PURPOSE

§ 58.122 Approved Plants under USDA inspection and grading service.

(a) Adoption of certain sound practices at dairy plants will significantly aid the operators to manufacture more consistently, uniform high-quality stable dairy products. Only dairy products manufactured, processed and packaged in an approved plant may be graded or inspected and identified with official identification. The specifications established herein provide the basis for a quality maintenance program which may be effectively carried forward through official inspection, grading, and quality control service.

(b) USDA inspection and grading service is provided to dairy product manufacturing plants on a voluntary basis. The operator of any dairy plant desiring to have such a plant qualified as an approved plant under USDA inspection and grading service may request surveys of such plant, premises, equipment, facilities, methods of operation, and raw material to determine whether they are adequate to permit inspection and grading service. The cost of this survey shall be borne by the applicant.

APPROVED PLANTS

§ 58.123 Survey and approval.

Prior to the approval of a plant, a designated representative of the Administrator shall make a survey of the plant, premises, storage facilities, equipment and raw material, volume of raw material processed daily, and facilities for handling the products at the plant. The survey shall be made at least twice a year to determine whether the facilities, equipment, method of operation, and raw material being received are adequate and suitable for USDA inspection and grading service in accordance with the provisions of this part. To be eligible for approval a plant shall satisfactorily meet the specifications of this subpart as determined by the Administrator.

§ 58.124 Denial or suspension of plant approval.

Plant approval may be denied or suspended if a determination is made by a designated representative of the Administrator that the plant is not performing satisfactorily in regard to; (a) the classification of milk, (b) proper segregation and disposal of unwholesome raw materials or finished product, (c) adequate facilities and condition of processing equipment, (d) sanitary conditions of plant and equipment, (e) control of insects, rodents and other vermin, (f) use of non-toxic product contact surfaces and prevention of adulteration of raw materials and products with chemicals or other foreign material, (g) proper

operating procedures, (h) the maintenance of legal composition of finished products, (i) the manufacture of stable dairy products, of desirable keeping quality characteristics, (j) proper storage conditions for ingredients and dairy products, or (k) suitable and effective packaging methods and material.

PREMISES, BUILDINGS, FACILITIES, EQUIPMENT AND UTENSILS

§ 58.125 Premises.

(a) The premises shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, smoke, or excessive air pollution. Construction and maintenance of driveways and adjacent plant traffic areas should be of cement, asphalt, or similar material to keep dust and mud to a minimum.

(b) *Surroundings.* The immediate surroundings shall be free from refuse, rubbish, overgrown vegetation, and waste materials to prevent harborage of rodents, insects and other vermin.

(c) *Drainage.* A suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent an environmental or health hazard.

§ 58.126 Buildings.

The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs, and cats. All service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

(a) *Outside doors, windows, openings, etc.* All openings to the outer air including doors, windows, skylights and transoms shall be effectively protected or screened against the entrance of flies and other insects, rodents, birds, dust and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors and windows should be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents, by the use of doors, screens, flaps, fans or tunnels. Outside openings for sanitary pipelines shall be covered when not in use. On new construction window sills should be slanted downward at approximately a 45° angle.

(b) *Walls, ceilings, partitions and posts.* The walls, ceilings, partitions, and posts of rooms in which milk, or dairy products are processed, manufactured, handled, packaged or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smoothly finished with a suitable material of light color, which is substantially impervious to moisture and kept clean. They shall be refinished as often as necessary to maintain a neat, clean surface. For easier cleaning new construction should have rounded cove at the juncture of the wall and floor in all receiving, pasteurizing, manufacturing, packaging and storage rooms.

(c) *Floors.* The floors of all rooms in which milk, or dairy products are processed, manufactured, packaged or stored or in which utensils are washed shall be constructed of tile properly laid with impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair. On new construction, bell and standpipe type traps shall not be used. The plumbing shall be so installed as to prevent the back-up of sewage into the drain lines and to the floor of the plant. Cold storage rooms used for storage of product and starter rooms need not be provided with floor drains if the floor is sloped to drain to an exit.

Sound, smooth, wood floors which can be kept clean, may be used in rooms where new containers and supplies and certain packaged finished products are stored.

(d) *Lighting and ventilation.* (1) Light shall be ample, natural or artificial, or both, of good quality and well distributed. All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces. Rooms where dairy products are graded or examined for condition and quality shall have at least 50 foot-candles of light intensity on the working surface. Restrooms and locker rooms should have at least 30 foot-candles of light intensity. In all other rooms there shall be provided at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of product by broken glass is possible, light bulbs and fluorescent tubes shall be protected against breakage.

(2) There shall be adequate heating, ventilation or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods or temperature and humidity control equipment shall be provided where and when needed, to minimize or control room temperatures, eliminate objectionable odors, and aid in prevention of moisture condensation and mold. Inlet fans should be provided with an adequate air filtering device to eliminate dirt and dust from the incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. Exhaust outlets shall be screened or provided with self closing louvers to prevent the entrance of insects when not in use.

(e) *Rooms and compartments.* Rooms and compartments in which any raw material, packaging, ingredient supplies or dairy products are handled, manufactured, packaged or stored shall be so designed, constructed and maintained as to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms, when present, shall be separated from the processing rooms by a wall. Rooms for receiving can milk shall be separated from the processing rooms by a partition or by suitable arrangement of equipment. Processing rooms shall be kept free from equipment and materials not regularly used.

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidity to adequately protect the product, and minimize the growth of mold. Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(2) *Supply room.* The supply rooms or areas used for the storing of packaging materials; containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold, and maintained in good repair. Such items stored therein shall be adequately protected from dust, dirt, or other extraneous material and so arranged on racks, shelves or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients or packaging supplies.

(3) *Boiler rooms, shop rooms and shop areas.* The boiler, and shop rooms shall be separated from other rooms where milk, and dairy products are processed, manufactured, packaged, handled or stored. Shop rooms or areas should be kept orderly and reasonably free from dust and dirt.

(4) *Toilet and dressing rooms.* Adequate toilet and dressing room facilities shall be conveniently located.—(a) Toilet rooms shall not open directly into any room in which milk or dairy products are processed, manufactured, packaged or stored; doors shall be self closing; ventilation shall be provided by mechanical means to the outer air; fixtures shall be kept clean and in good repair. (b) All employees shall be furnished with a locker or other suitable facility and the lockers and dressing rooms shall be kept clean and orderly. Adequate handwashing facilities shall be provided. Legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory.* (i) Consistent with the size and type of plant and the volume of dairy products manufactured, an adequately equipped laboratory shall be maintained and properly staffed with qualified and trained personnel for quality control and analytical testing. The laboratory should be located reasonably close to the processing activity and be of sufficient size to perform tests necessary in evaluating the quality of raw and finished products.

(ii) Approved laboratories shall be supervised by the USDA resident inspector in all aspects of official testing and reporting results. Plant laboratory personnel in such plants may be licensed by the USDA to perform official duties.

(iii) An approved central control laboratory serving more than one plant may be acceptable, if conveniently located to the dairy plants, and if samples and results can be transmitted without undue delay.

(6) *Starter facilities.* Adequate facilities shall be provided for the handling of starter cultures. The facilities shall not be located near areas where contamination is likely to occur.

(7) *Grading and inspection room.* When grading or inspection of product is performed the plants shall furnish a room or designated area specifically for this purpose. The room or area shall be suitably located, sufficient in size, well lighted (see 58.126d), ventilated and the temperature shall be not less than 60° F. It shall be kept clean and dry, free from foreign odors and reasonably free from disturbing elements which would interfere with proper concentration by the grader or inspector. The grading or inspection room or area shall be equipped with a table or desk and convenient facilities for washing hands.

(8) *Resident inspector's facilities.* In resident plants, an office or space shall be provided for official purposes. The room or space should be conveniently located in or near the approved laboratory, adequate in size, and equipped with desk and a lockable storage supply cabinet, and clothes locker. It shall be well lighted, ventilated or air conditioned, and heated. Custodial service shall be furnished on a regular basis.

(9) *Lunch rooms and eating areas.* When these areas are provided, they (a) shall be kept clean and orderly, (b) should not open directly into any room in which milk or dairy products are processed, manufactured or packaged, and (c) signs shall be posted directing employees to wash their hands before returning to work.

§ 58.127 Facilities.

(a) *Water supply.* There shall be an ample supply of both hot and cold water of safe and sanitary quality, with adequate facilities for its proper distribution throughout the plant, and protected against contamination. Water from other facilities, when officially approved, may be used for boiler feed water and condenser water provided that such water lines are completely separated from the water lines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There shall be no cross connection between potable water lines and non-potable water lines or between public and private water supplies. Bacteriological examinations shall be made of the plant's sanitary water supply taken at the plant at least twice a year, or as often as necessary to determine safety and suitability as related to product keeping quality for use in manufacucts keeping quality for use in manube made by a USDA or State agency laboratory except for supplies that are regularly tested for purity and bacteriological quality, and approved by the local health officer. The results of all water tests shall be kept on file at the plant for which the test was performed.

The location, construction, and operation of any well shall comply with regulations of the appropriate agency.

(b) *Drinking-water facilities.* Drinking-water facilities of a sanitary type shall be provided in the plant and should be conveniently located.

(c) *Hand-washing facilities.* Convenient hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single service towels or air driers. Such accommodations shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as hand-washing facilities. Containers shall be provided for used towels and other wastes. The containers may be metal or plastic, disposable or reuseable and should have self-closing covers.

(d) *Steam.* Steam shall be supplied in sufficient volume and pressure for satisfactory operation of each applicable piece of equipment. Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and only those boiler water additives which meet the requirements of 21 CFR 121.1088 shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used. Steam traps, strainers and condensate traps shall be used wherever applicable to insure a satisfactory and safe steam supply. Culinary steam shall comply with the recommended practices for "Producing Culinary Steam for Processing Milk and Milk Products" as published by the National Association of Food and Dairy Equipment Manufacturers, Washington, D.C., April 1963 or latest revision thereof.

(e) *Air under pressure.* The method for supplying air under pressure, which comes in contact with milk or dairy products or any product contact surface shall comply with the 3–A Accepted Practices for Supplying Air Under Pressure.

(f) *Disposal of wastes.* Dairy wastes shall be properly disposed of from the plant and premises consistent with requirements imposed by the Environmental Protection Act. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tight fitting lids. Waste shall be stored in an area or room in a manner to protect it from flies and vermin. Solid wastes shall be disposed of regularly and the containers cleaned before re-use. Accumulation of dry waste paper and cardboard shall be kept to a minimum and disposed of in a manner that is environmentally acceptable.

§ 58.128 Equipment and utensils.

(a) General construction, repair and installation.—The equipment and utensils used for the processing of milk and manufacture of dairy products shall be constructed to be readily demountable where necessary for cleaning and sanitizing. The product contact surfaces of all utensils and equipment such as holding tanks, pasteurizers, coolers, vats, agitators, pumps, sanitary piping and fittings or any specialized equipment shall be constructed of stainless steel, or other materials which under conditions of intended use are as equally corrosion resistant. Non-metallic parts other than glass having product contact surfaces shall comply with 3–A Sanitary Standards for Plastic or Rubber and Rubber-Like Materials. Equipment and utensils used for cleaning shall be in an acceptable condition, such as not rusty, pitted or corroded. All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment, shall be set away from any wall or spaced in such a manner as to facilitate proper cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned-in-place) or fittings, including valves and connections shall be accessible for inspection. Milk and dairy product pumps shall be of a sanitary type and easily dismantled for cleaning or shall be of specially approved construction to allow effective cleaning in place.

All C.I.P. systems shall comply with the 3–A Accepted Practices for Permanently Installed Sanitary Product, Pipelines and Cleaning Systems.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall comply with the 3–A Sanitary Standards for Weigh Cans and Receiving Tanks for Raw Milk and shall be easily accessible for cleaning both inside and outside and shall be elevated above the floor and protected sufficiently with the necessary covers or baffles to prevent contamination from splash, condensate and drippage. Where necessary to provide easy access for cleaning of floors and adjacent wall areas, the receiving tank shall be equipped with wheels or casters to allow easy removal.

(c) *Can washers.* Can washers shall have sufficient capacity and ability to discharge a clean dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. They should be equipped with proper temperature controls on the wash and rinse tanks and the following additional devices: prerinse jet, wash tank solution feeder, can sanitizing attach-

ment, forced air vapor exhaust, and removable air filter on drying chamber. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves. The steam pressure to the can washer should be not less than 80 pounds, and the temperature of the wash and final rinse solution should be automatically controlled and not exceed 140° F.

(d) *Product storage tanks or vats.* Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be suitably protected against the entrance of dust, moisture, insects, oil or grease. The sight glasses, if used, shall be sound, clear, and in good repair. Vats which have hinged covers shall be easily cleaned and shall be so designed that moisture, or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the 3–A Accepted Practices for Supplying Air Under Pressure. Storage tanks or vats intended to hold product for longer than approximately 8 hours shall be equipped with adequate refrigeration and/or have adequate insulation. New or replacement storage tanks or vats shall comply with the appropriate 3–A Sanitary Standards for Storage Tanks for Milk and Milk Products or Sanitary Standards for Silo-Type Storage Tanks for Milk and Milk Products and shall be equipped with thermometers in good operating order.

(e) *Separators.* All product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals.

(f) *Coil or dome type batch pasteurizers.* Coil or dome type batch pasteurizers shall be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it shall be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats shall be of the removable type, except that existing equipment not provided with this type gland will be acceptable if the packing glands are maintained and operated without adverse effects. New or replacement units shall be provided with removable packing glands. Dome type pasteurizer agitators shall be stainless steel except that any non-metallic parts shall comply with 3–A Sanitary Standards for Plastic or Rubber and Rubberlike Materials, as applicable. Each pasteurizer used for heating product at a temperature of 5° F. or more above the minimum pasteurization temperature need not have the air-space heater. It shall be equipped with an air-space thermometer to insure a temperature at least 5° F. above that required for pasteurization of the product. There shall be adequate means of controlling the temperature of the heating medium. Batch pasteurizers shall have temperature indicating and recording devices.

(g) *Short time pasteurizing systems.* When pasteurization is intended or required, an approved timing pump or device, recorder-controller, automatic flow diversion valve and holding tube or its equivalent, if not a part of the existing equipment, shall be installed on all such equipment used for pasteurization, to assure complete pasteurization. The entire facility shall comply with the 3–A Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High Temperature Short Time Pasteurizers. After the unit has been tested according to the 3–A Accepted Practices, the timing pump or device and the recorder controller shall be sealed at the correct setting to assure pasteurization. The system should be rechecked semi-annually to assure continued compliance with the 3–A Accepted Practices. Sealing and rechecking of the unit shall be performed by the control authority having jurisdiction. When direct steam pasteurizers are used, the steam, prior to entering the product, shall be conducted through a steam strainer and a steam purifier equipped with a steam trap and only steam meeting the requirements for culinary steam shall be used.

(h) *Thermometers and recorders.* (1) *Indicating thermometers.* (i) Long stem indicating thermometers which are accurate within 0.5° F., plus or minus, for the applicable temperature range, shall be provided for checking the temperature of pasteurization and cooling of products in vats and checking the accuracy of recording thermometers.

(ii) Short stem indicating thermometers, which are accurate within 0.5° F., plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0° F., plus or minus.

(iii) Air space indicating thermometers, where applicable, which are accurate within 1.0° F., plus or minus, for the proper temperature range shall also be installed above the surface of the products pasteurized in vats, to make certain that the temperature of the foam and/or air above the products pasteurized also received the required minimum temperature treatment.

(2) *Recording thermometers.* (i) Recording thermometers that are accurate within 1° F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing or thermal processing unit to record the heating process.

(ii) Additional use of recording thermometers accurate within 2° F., plus or minus may be required where a record of temperature or time of cooling and holding is of significant importance.

(iii) Recorder charts shall be marked to show date and plant identification, reading of the indicating thermometer at a particular referenced reading point on the recording chart, amount and name of product, product temperature at which the "cut-in" and "cut-out" function, record of the period in which flow diversion valve is in forward-flow position, signature or initials of operator.

(i) *Surface coolers.* Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on non-product contact surfaces away from product contact surfaces. All gaskets or swivel connections shall be leak proof.

(j) *Plate type heat exchangers.* Plate type heat exchanger shall comply with the 3–A Sanitary Standards Plate Type Heat Exchangers for Milk and Milk Products. All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen should be posted to insure proper cleaning procedures between inspection periods.

(k) *Internal return tubular heat exchangers.* Internal return tubular heat exchangers shall comply with the 3–A Sanitary Standards for Internal Return Tubular Heat Exchangers for Use with Milk and Milk Products.

(l) *Pumps.* Pumps used for milk, and dairy products shall be of the sanitary type and constructed to comply with 3–A Sanitary Standards for Pumps for Milk and Milk Products. Unless pumps are specifically designed for effective cleaning-in-place they shall be disassembled and thoroughly cleaned after use.

(m) *Scales.* All scales shall comply with National Bureau of Standards Handbook 44. (Latest revision).

(1) Small capacity scales shall be capable of the following accuracy, and shall be graduated in no higher than one ounce graduations. (This table taken from the presently effective 1973 revision.)

	Minimum tolerance	
	Ounces	Pounds
Load in pounds:		
0 to 4 inclusive	1/32	0.002
5 to 10 inclusive	1/16	.004
11 to 20 inclusive	1/8	.008
21 to 30 inclusive	3/16	.012
31 to 50 inclusive	1/4	.031
51 to 500 inclusive	3/4	.047

(2) Large capacity scales shall be capable of the following accuracy, and shall be graduated in no higher than ¼ pound graduations for scales of capacity of up to 250 pounds; ½ pound graduations for scales above 250 pounds capacity.

(This table taken from the presently effective 1973 revision.)

	Minimum tolerance	
	Ounces	Pounds
Load in pounds:		
101 to 150 inclusive	1¼	0.078
151 to 250 inclusive	2	.125
251 to 500 inclusive	4	.250
501 to 1000 inclusive	8	.500
1001 to 2500 inclusive		1.0

Compliance shall be determined by the appropriate regulatory authority.

(n) *Homogenizers.* Homogenizers and high pressure pumps of the plunger type shall comply with the 3–A Sanitary Standards for Homogenizers and Pumps of the Plunger Type and shall be disassembled and thoroughly cleaned after use.

(o) *New equipment and replacements.* New equipment and replacements, including all plastic parts and rubber and rubberlike materials for parts and gaskets having product contact surfaces, shall comply with the then current 3–A Sanitary Standards. If 3–A Sanitary Standards are not available, such equipment and replacements shall meet the general requirements of this section. Only material that is sanitary, readily cleanable and non-toxic shall be used for product contact surfaces, parts and gaskets.

(p) *Vacuumizing equipment.* The vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally corrosion resistant metal. The unit shall be constructed to facilitate cleaning and all product contact surfaces shall be accessible for inspection. Vacuum chambers located on the pasteurized side of the unit shall be isolated by means of a vacuum breaker and a positive activated check valve on the product inlet side and a vacuum breaker and a positive activated check valve on the discharge side. If direct steam is used, it should also be equipped with a ratio controller to regulate the composition when applicable to the finished product. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow diversion valve of the pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

PERSONNEL, CLEANLINESS AND HEALTH

§ 58.129 Cleanliness.

All employees shall wash their hands before beginning work and upon return-eating, smoking or otherwise soiling their ing to work after using toilet facilities, hands. They shall keep their hands clean and follow good hygienic practices while on duty. Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy products, or supplies are prepared, stored or otherwise handled. Clean white or light-colored washable or disposable outer garments and caps (paper caps, hard hats, or hair nets acceptable) shall be worn to adequately protect the hair and beards when grown by all persons engaged in receiving, testing, processing milk, manufacturing, packaging or handling dairy products.

§ 58.130 Health.

No person afflicted with a communicable disease shall be permitted in any room or compartment where milk and dairy products are prepared, manufactured or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms or other exposed portion of the body shall work in any dairy processing rooms or in any capacity resulting in contact with milk, or dairy products. Each employee whose work brings him in contact with the processing or handling of dairy products, containers or equipment should have a medical and physical examination by a registered physician or by the local department of health at the time of employment. An employee returning to work following illness from a communicable disease shall have a certificate from the attending physician to establish proof of complete recovery.

PROTECTION AND TRANSPORT OF RAW MILK AND CREAM

§ 58.131 Equipment and facilities.

(a) (1) *Milk cans.* Cans used in transporting milk from dairy farm to plant shall be of such construction (preferably seamless with umbrella lids) as to be easily cleaned, and shall be inspected, repaired, and replaced as necessary to exclude substantially the use of cans and lids with open seams, cracks, rust, milkstone, or any unsanitary condition. Adequate provisions should be made so that milk in cans will be cooled immediately after milking to 50° F. or lower unless delivered to the plant within two hours after milking.

(2) *Farm bulk tanks.* Farm bulk tanks shall comply with 3–A Sanitary Farm Cooling and Holding Tanks or 3–A Sanitary Standards for Farm Cooling and Holding Tanks or 3–A Sanitary Standards for Farm Milk Storage Tanks as applicable. They shall be installed in a milk house in accordance with the requirements of the regulatory agency in jurisdiction. The bulk cooling tanks shall be designed and equipped with refrigeration to permit the cooling of the milk to 40° F. or lower within two hours after milking, and maintain it at 45° F. or below until picked up.

(b) (1) *Receiving stations.* Receiving stations shall comply with the applicable sections of this subpart covering premises, buildings, facilities, equipment, utensils, personnel, cleanliness and health.

(2) *Transfer stations.* Transfer stations shall comply with the applicable sections of this subpart covering premises, floors, lighting, water supply, hand-washing facilities, disposal of wastes, general construction, repair and installation of equipment, piping and utensils and personnel—cleanliness and health. As climatic and operating conditions require the transfer station shall comply with the applicable sections for walls ceilings, doors and windows.

(3) *Cream stations.* Cream stations shall provide adequate protection and facilities for the handling, transferring and cooling of farm separated cream. The area shall be large enough to avoid undue crowding with a normal volume of business and shall be separated from other areas and the outside by self closing, tight fitting doors. All openings shall be screened during fly season. The floor, walls and ceiling shall be of satisfactory construction, in good repair and kept clean. Lighting and ventilation shall meet the requirements of section 58.126 (d). Cooling facilities shall be provided to cool the cream to 50° F. or lower unless shipped within 8 hours after receipt. Facilities shall be provided to wash, sanitize and store cans and equipment used in the operation. The cream should not be more than four days old when picked up for delivery to the processing plant.

(c) (1) *Transporting milk or cream.* Vehicles used for the transportation of can milk or cream shall be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and they shall be kept clean. Decking boards or racks shall be provided where more than one tier of cans is carried. Cans or vehicles used for the transportation of milk from the farm to the plant shall not be used for transporting skim milk, buttermilk, or whey to producers.

(2) *Transport tanks.* The exterior shell shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and so constructed that it will not buckle, sag or prevent complete drainage. All product contact surfaces shall be smooth, easily cleaned and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with dust covers to give adequate protection from road dust. Tank manholes should be equipped with an adequate filtering system during loading and unloading. New and replacement transport tanks shall comply with 3–A Sanitary Standards for Stainless Steel Automotive Milk and Milk Products Transportation Tanks for Bulk Delivery and/or Farm Pick-up Service.

(3) *Facilities for cleaning and sanitizing.* Enclosed or covered facilities (as climatic conditions require) shall be available for washing and sanitizing of transport tanks, piping, and accessories, at central locations or at all plants that receive or ship milk or milk products in transport tanks.

(d) *Transfer of milk to transport tank.* Milk shall be transferred under sanitary conditions from farm bulk tanks through stainless steel piping or approved tubing. The sanitary piping and tubing shall be capped when not in use.

QUALITY SPECIFICATIONS FOR RAW MILK

§ 58.132 Basis for classification.

Raw milk for manufacturing purposes, from all individual producers, shall be based on the following: organoleptic examination (appearance and odor), quality control tests for sediment content, and bacterial estimate. In addition, milk from cows treated with antibiotics shall be excluded for such period of time as is necessary to have the milk free from antibiotics. All milk received from producers shall not exceed Federal Food and Drug Administration's established limits for pesticide residues. Producers shall

be promptly notified of any shipment or portion thereof of their milk that fails to meet any of these quality specifications.

§ 58.133 Methods for quality and wholesomeness determination.

(a) *Appearance and odor.* The appearance and odor of acceptable raw milk shall be normal, fresh and sweet. The milk shall be free from objectionable feed and other off-odors that would adversely affect the finished product, and it shall not show any abnormal condition (including, but not limited to curdled, ropy, bloody, or mastitic condition), as indicated by sight, odor, or other test procedures.

(b) *Abnormal milk.* (1) A laboratory examination for the presence of unwholesome mammary secretions—whether of an inflammatory, infectious, physiological, or environmental origin—shall be made on all patrons milk at least 4 times in each 6 month period at irregular intervals.

(2) When a herd milk sample exceeds any of the following screening test results:

(i) California Mastitis Test—Weak Positive (CMT 1+).

(ii) Modified Whiteside Test—Positive (1+).

(iii) Wisconsin Mastitis Test—WMT Value of 21mm or as an alternative, each laboratory will establish its own WMT score above which confirmatory testing will be done.

A somatic cell count using the Direct Microscopic Count Method or equivalent, or the Electronic Method shall be made on that sample and the results of the somatic cell direct count shall be the official result.

(3) Whenever the somatic cell count indicates the presence of more than 1,500,000 somatic cells per ml., the following procedures shall be applied:

(i) A notice shall be sent to the producer warning him of the excessive somatic cell count.

(ii) Whenever two of the last four consecutive somatic cell counts exceed 1,500,000 cells per ml. the appropriate regulatory authority shall be notified and a written notice given to the producer. This notice shall be in effect so long as two of the last four consecutive samples exceed 1,500,000 cells per ml. In addition to the written notice an inspection shall be made of the farm facility.

(4) A third milk sample shall be taken after a lapse of 3 days and within 14 days of the inspection required under (2) above. If this sample also indicates a high somatic cell count, the patron's milk shall be rejected until satisfactory compliance is obtained.

(c) *Antibiotics.* At least 4 times in 6 months, at irregular intervals, a separate or commingled sample of each producer's milk shall be tested for antibiotic residues. When a producer's milk shows a positive test the milk shall be immediately rejected from all markets and shall not be accepted until a subsequent test is negative.

§ 58.134 Sediment content.

(a) *Method of testing.* Methods for determining sediment content of milk shall be those described in the latest edition of Standard Methods for the Examination of Dairy Products. For the testing of milk in cans, the off-the-bottom method shall be used. For testing bulk milk, a mixed one-pint sample shall be tested. Sediment content shall be based on comparison with applicable charts of Sediment Standards described in Subpart T 58.2728 through 58.2731 of this part.

(b) *Sediment content classification of discs.* Milk in cans and in farm bulk tanks shall be classified for sediment content as follows:

(1) Sediment (off - the - bottom method): (1⅛ inch diameter disc).

No. 1—USDA Sediment Standard (not to exceed) 0.50 mg. (Acceptable).

No. 2—USDA Sediment Standard (not to exceed) 1.50 mg. (Acceptable).

No. 3—USDA Sediment Standard (not to exceed) 2.50 mg. (Probational) not over 10 days.

No. 4—USDA Sediment Standard (over 2.50 mg.) (Reject).

(2) Sediment (mixed sample): (0.40 inch diameter disc).

No. 1—USDA Sediment Standard (not to exceed) 0.0625 mg. (0.50 mg. equiv.) (Acceptable).

No. 2—USDA Sediment Standard (not to exceed) 0.1875 mg. (1.50 mg. equiv.) (Acceptable).

No. 3—USDA Sediment Standard (not to exceed) 0.3125 mg. (2.50 mg. equiv.) (Probational) not over 10 days.

No. 4—USDA Sediment Standard (over) 0.3125 mg. (2.50 mg. equiv.) (Reject).

(c) *Frequency of tests.* At least once each month, at irregular intervals, the milk from each producer shall be tested as follows:

(1) *Milk in cans.* One or more cans of milk selected at random from each producer.

(2) *Milk in farm bulk tanks.* A sample shall be taken from each farm bulk tank.

(d) *Acceptance or rejection of milk.* If the sediment disc is classified as No. 1, No. 2, or No. 3 the producer's milk may be accepted. If the sediment disc is classified No. 4 the milk shall be rejected: *Provided that* if the shipment of milk is commingled with other milk in a transport tank the next shipment shall not be accepted until its quality has been determined before being picked up; however, if the person making the test is unable to get to the farm before the next shipment it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, if in cans, all cans shall be tested. Producers of No. 3 or No. 4 milk (cans or bulk) shall be notified immediately and shall be furnished applicable sediment discs and the next shipment shall be tested.

(e) *Retests.* On test of the next shipment (if in cans, all cans shall be tested) milk classified as No. 1, No. 2, or No. 3 may be accepted, but No. 4 milk shall be rejected. Retests of bulk milk classified as No. 4 shall be made before pickup. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment tested.

This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not more than 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be rejected.

§ 58.135 Bacterial estimate.

(a) *Method of testing.* Methods for determining the bacterial estimate of milk shall be those described in the latest edition of Standard Methods for the Examination of Dairy Products.

(b) *Bacterial estimate classification.* Milk shall be classified for bacterial estimate by one of the following methods:

Bacterial estimate classification	Direct microscopic count, standard plate count or plate loop count	Resazurin reduction time to Munsell color standard 5 P 7/4
No. 1:		
Can	Not over 500,000 per milliliter.	Not less than 2¼ hours.
Bulk	do	Not less than 3¼ hours.
No. 2:		
Can	Not over 3,000,000.	Not less than 1½ hours.
Bulk	do	Not less than 2½ hours.
Undergrade:		
Can	Over 3,000,000	Less than 1½ hours.
Bulk	do	Less than 2½ hours.

(c) *Frequency of tests.* At least once each month, at irregular intervals, a mixed sample of each producer's milk shall be tested.

(d) *Acceptance of milk.* If the sample of milk is classified as No. 1 or No. 2 the producer's milk may be accepted without qualification. If the sample is classified as "Undergrade" (probational) the producer's milk may be accepted for a temporary period of four weeks. The producer of "Undergrade" milk shall be notified immediately.

(e) *Retests.* Additional samples shall be tested and classified at least weekly and the producer notified immediately of the results. This procedure of testing at least weekly and accepting "Undergrade" milk may be continued for a time period not exceeding four weeks. If at the end of this time the producer's milk does not meet the acceptable bacterial estimate requirements (No. 1 or No. 2), it shall not be accepted.

§ 58.136 Rejected milk.

A plant shall reject specific milk from a producer if it fails to meet the requirements for appearance and odor (section 58.133(a)) or if it is classified No. 4 for sediment content (section 58.134). Such milk shall be identified with a reject tag.

§ 58.137 Excluded milk.

A plant shall not accept milk from a producer for use in products:

(a) If a new producer's milk does not meet the requirements for appearance and odor (§ 58.133(a)) or sediment content (§ 58.134); or

(b) If the milk has been in a probational (No. 3) sediment content classification for more than ten calendar days (§ 58.134); or

(c) If the milk has been classified "Undergrade" for bacterial estimate for more than four successive weeks (section 58.135).

(d) If the milk has been classified as having a high somantic cell count (§ 58.133(b)(4)) or having a positive test for antibiotics (§ 58.133(c)).

§ 58.138 Quality testing of milk from new producers.

An examination shall be made on the first shipment of milk from producers shipping milk to a plant for the first time or after a period of nonshipment. The milk shall meet the requirements for "acceptable milk" (§§ 58.133, 58.134, and 58.135). Thereafter, the milk shall be tested in accordance with the procedure established for regular shippers.

§ 58.139 Record of tests.

Accurate records, listing the results of quality tests of each producer, shall be kept on file at the receiving plant where performed and shall be available for examination by the inspector.

§ 58.140 Field service.

A representative of the plant should arrange to promptly visit each producer shipping milk which does not meet the requirements for acceptable milk, for the purpose of inspecting the equipment, utensils and facilities at the farm and to offer constructive assistance for improvement in the quality of the milk. A representative of the plant should visit each producer as often as practicable to assist in and encourage the production of high quality milk.

§ 58.141 Alternate quality control program.

When a plant has in operation an acceptable quality program, at the producer level, which is approved by the Administrator as being effective in obtaining results comparable to or higher than the quality program as outlined above for milk or cream, then such a program may be accepted in lieu of the program herein prescribed.

OPERATIONS AND OPERATING PROCEDURES

§ 58.142 Product quality and stability.

The receiving, holding and processing of milk and cream and the manufacturing, handling, packaging, storing and delivery of dairy products shall be in accordance with clean and sanitary methods, consistent with good commercial practices to promote the production of the highest quality of finished product and improve product stability. Milk should not be more than three days old when picked up from the producer and delivered to the plant, receiving station or transfer station.

§ 58.143 Raw product storage.

All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers and any other source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45° F. or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

The bacteriological quality of commingled milk in storage tanks shall not exceed 3,000,000/ml.

§ 58.144 Pasteurization or ultra-pasteurization.

When pasteurization or ultra-pasteurization is intended or required, or when a product is designated "pasteurized" or "ultra-pasteurized" every particle of the product shall be subjected to such temperatures and holding periods in approved systems as will assure proper pasteurization or ultra-pasteurization of the product. The heat treatment by either process shall be sufficient to insure public health safety and to assure adequate keeping quality, yet retaining the most desirable flavor and body characteristics of the finished product.

§ 58.145 Composition and wholesomeness.

All necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. All substances and ingredients used in the processing or manufacturing of any dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act as to their composition and wholesomeness.

§ 58.146 Cleaning and sanitizing treatment.

(a) *Equipment and utensils.* The equipment, sanitary piping and utensils used in receiving and processing of the milk, and manufacturing and handling of the product shall be maintained in a sanitary condition. Sanitary seal assemblies shall be removable on all agitators, pumps, and vats and shall be inspected at regular intervals and kept clean. Unless other provisions are recommended in the following supplement sections, all equipment not designed for C. I. P. cleaning or mechanical cleaning shall be disassembled after each day's use for thorough cleaning. Dairy cleaners, detergents, wetting agents or sanitizing agents, or other similar materials which will not contaminate or adversely affect the products may be used. Steel wool or metal sponges shall not be used in the cleaning of any dairy equipment or utensils.

Product contact surfaces shall be subjected to an effective sanitizing treatment prior to use, except where dry cleaning is permitted. Utensils and portable equipment used in processing and manufacturing operations shall be stored above the floor in clean, dry locations and in a self draining position on racks constructed of impervious corrosion-resistant material.

C.I.P. cleaning or mechanical cleaning systems shall be used only on equipment and pipeline systems which have been designed, engineered and installed for that purpose. When such cleaning is used, careful attention shall be given to the proper procedures to assure satisfactory cleaning. All C.I.P. installations and cleaning procedures shall be in accordance with 3–A Suggested Method for the Installation and Cleaning of Cleaned-In-Place Sanitary Milk Pipelines for Milk and Milk Products Plants. Because of the possibilities of corrosion, the recommendations of the cleaning compound manufacturer should be followed with respect to time, temperature and concentration of specific acid or alkaline solutions and bactericides. Such cleaning operation should be preceded by a thorough rinse at approximately 110–115° F. continuously discarding the water. Following the circulation of the cleaning solution the equipment and lines shall be thoroughly rinsed with lukewarm water and checks should be made for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends, pumps, and tee ends shall be opened or removed and brushed clean. All non-pasteurized product contact surfaces should be sanitized. Immediately prior to starting the product flow, the pasteurized product contact surfaces shall be given sanitizing treatment.

(b) *Milk cans and can washers.* Milk cans and lids shall be cleaned, sanitized and dried before returning to producers. Inspection, repair or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or any unsanitary condition.

Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer. Only washing compounds which are compatible with the water for effective cleaning, should be used. The can washer should be checked regularly during the run for proper operation. At the end of the day, the wash and rinse tanks should be drained and cleaned, jets and strainers cleaned, air filters checked and changed or cleaned if needed, and checks should be made for proper adjustment and condition of mechanical parts.

(c) *Milk transport tanks.* A covered or enclosed wash dock and cleaning and sanitizing facilities shall be available to all plants that receive or ship milk in tanks. Milk transport tanks, sanitary piping, fittings, and pumps shall be cleaned and sanitized at least once each day after use: provided that, if they are not to be used immediately after empty-

ing a load of milk, they shall be washed promptly after use and given bactericidal treatment immediately before use. After being washed and sanitized, each tank should be identified by a tag attached to the outlet valve, bearing the following information: plant and specific location where cleaned, date and time of day of washing and sanitizing, and name of person who washed and name of person who sanitized the tank. The tag shall not be removed until the tank is again washed and sanitized.

(d) *Building.* All windows, glass, partitions, and skylights should be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings and doors should be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges should be wiped or vacuumed as often as necessary to keep them free from dust and debris. The material picked up by the vacuum cleaners shall be disposed of in sealed containers which will prevent contamination or insect infestation from the waste material.

§ 58.147 Insect and rodent control program.

In addition to any commercial pest control service, if one is utilized, a specially designated employee should be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances shall be properly labeled, and shall be handled, stored and used in such a manner as considered satisfactory by the Environmental Protection Agency..

§ 58.148 Plant records.

Adequate plant records shall be maintained of all required tests and analyses performed in the laboratory or throughout the plant during storage, processing and manufacturing, on all raw milk receipts and dairy products. Such records shall be available for examination at all reasonable times by the inspector. The following are the records which shall be maintained for examination at the plant or receiving station where performed.

(a) Sediment and bacterial test results on raw milk from each producer. Retain for 12 months.

(1) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(2) Retests, if initial test places milk in probationary status.

(3) Rejections of raw milk over No. 3 in quality.

(b) Pasteurization recorder charts. Retain for 3 months.

(c) Water supply test certificate. Retain current copy for 6 months.

(d) Cooling and heating recorder charts. Retain for 3 months.

§ 58.149 Alternate quality control programs for dairy products.

(a) When a plant has in operation an acceptable quality control program which is approved by the Administrator as being effective in obtaining results comparable to or higher than the quality control program as outlined in this subpart, then such a program may be accepted in lieu of the program herein prescribed.

(b) Where a minimum number of samples per batch of product, or per unit of time on continuous production runs are not specified, the phrase "as many samples shall be taken as is necessary to assure compliance to specific quality requirements" is used. Acceptable performance of this would be any method approved by the Administrator as meeting sound statistical methods of selecting samples and determining the number of samples to be taken.

PACKAGING AND GENERAL IDENTIFICATION

§ 58.150 Containers.

The size, style, and type of packaging used for dairy products shall be commercially acceptable containers and packaging materials which will satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling.

Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. In addition, the wrapper should be resistant to puncturing, tearing, cracking or breaking under normal conditions of handling, shipping and storage. When special type packaging is used, the instructions of the manufacturer shall be followed closely as to its application and methods of closure.

§ 58.151 Packaging and repackaging.

Packaging dairy products or cutting and repackaging all styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and packaging materials shall be practically free from mold and bacterial contamination. Methods for checking the level of contamination shall be as prescribed by the latest edition of Standard Methods or by other satisfactory methods approved by the Administrator.

When officially graded bulk dairy products are to be repackaged into consumer type packages with official grade labels or other official identification, a supervisor of packaging shall be required, see Subpart A of this part. (Title 7, Ch. I, Pt. 58, sec. 58.2 and 58.53 of the Code of Federal Regulations). If the packaging or repackaging is done in a plant other than the one in which the dairy product is manufactured, the plant, equipment, facilities and personnel shall meet the same requirements as outlined in this subpart.

§ 58.152 General identification.

All commercial bulk packages or consumer packaged product containing dairy products manufactured under the provisions of this subpart shall comply with the applicable regulation of the Food and Drug Administration.

STORAGE OF FINISHED PRODUCT

§ 58.153 Dry storage.

The product should be stored at least 18 inches from the wall in aisles, rows, or sections and lots, in such a manner as to be orderly and easily accessible for inspection. Rooms should be cleaned regularly. It is recommended that dunnage or pallets be used when practical. Care shall be taken in the storage of any other product foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, or vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

§ 58.154 Refrigerated storage.

Finished product in containers subject to such conditions that will affect its useability shall be placed on shelves, dunnage or pallets and properly identified. It shall be stored under temperatures that will best maintain the initial quality. The product shall not be exposed to anything from which it might absorb any foreign odors or be contaminated by drippage or condensation.

INSPECTION, GRADING AND OFFICIAL IDENTIFICATION

§ 58.155 Grading.

Dairy products which have been processed or manufactured in accordance with the provisions of this subpart may be graded by the grader in accordance with the U.S. Standards for Grades. Laboratory analyses, when required in determining the final grade shall be conducted in an approved laboratory.

§ 58.156 Inspection.

Dairy products, which have been processed or manufactured in an approved plant, and for which there are no official U.S. Standards for Grades, shall be inspected for quality by the inspector in accordance with contract requirements or product specifications established by the U.S. Department of Agriculture or other Federal agency or buyer and seller. Laboratory analysis when required shall be conducted in an approved laboratory.

§ 58.157 Inspection or grading certificates.

All dairy products which have been processed or manufactured, packaged and inspected or graded in accordance with the provision of this part may be covered by an inspection or grading certificate issued by the inspector or grader.

§ 58.158 Official identification.

(a) Application for authority to apply official identification to packaging material or containers shall be made in accordance with the provisions of Subpart A of this part. (Title 7, Ch. I, Pt. 58, secs. 58.49–58.57 of the Code of Federal Regulations.)

(b) Only dairy products received, processed, or manufactured in accordance with the specifications contained in this subpart and inspected and/or graded in accordance with the provisions of this part may be identified with official identification.

EXPLANATION OF TERMS

§ 58.159 Terms.

(a) *Fresh and sweet.* Free from "old milk" flavor of developed acidity or other off-flavors.

(b) *Normal feed.* Regional feed flavors, such as alfalfa, clover, silage, or similar feeds or grasses (weed flavors, such as peppergrass, French weed, onion, garlic, or other obnoxious weeds, excluded).

(c) *Off-flavors.* Tastes or odors, such as utensil, bitter, barny, or other associated defects when present to a degree readily detectable.

(d) *Developed acidity.* An apparent increase from the normal acidity of the milk to a degree of taste and odor which is detectable.

(e) *Extraneous matter.* Foreign substances, such as filth, hair, insects and fragments thereof, and rodents, and materials, such as metal, fiber, wood and glass.

(f) *Sediment.* Fine particles of material other than the foreign substances and materials defined in paragraph (e) of this section.

(g) *C.I.P.* The abbreviation of an approved system of cleaning pipelines called "Cleaned-in-Place."

(h) *Mechanical cleaning.* Denotes cleaning solely by circulation and/or flowing chemical detergent solution and water rinses onto and over the surfaces to be cleaned, by mechanical means.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING NONFAT DRY MILK, INSTANT NONFAT DRY MILK, DRY WHOLE MILK, AND DRY BUTTERMILK

DEFINITIONS

§ 58.205 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Nonfat dry milk.* The pasteurized product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It shall not contain buttermilk, or any added preservative, neutralizing agent or other chemical.

(b) *Instant nonfat dry milk.* Nonfat dry milk which has been produced in such a manner as to substantially improve its dispersing and reliquification characteristics over that produced by the conventional process.

(c) *Dry whole milk.* The pasteurized product resulting from the removal of water from milk and contains the lactose, milk proteins, milk fat, and milk minerals in the same relative proportions as in the fresh milk from which made. The milk may be standardized but shall not contain buttermilk, or any added preservative, neutralizing agent or other chemicals.

(d) *Dry buttermilk.* The product resulting from drying liquid buttermilk, derived from the manufacture of sweet cream butter, which has been pasteurized either before or during the process of manufacture, with or without the addition of lactic culture and to which no alkali or other chemical preservatives has been added.

ROOMS AND COMPARTMENTS

§ 58.210 Dry storage of product.

Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams and floors should be free from structural defects and inaccessible false areas which may harbor insects.

§ 58.211 Packaging room for bulk products.

A separate room or area shall be provided for filling bulk containers, and shall be constructed in accordance with section 58.126. The number of control panels and switch boxes in this area should be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or satisfactorily sealed to the wall, or shall be mounted in the wall and provided with tight fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the accumulation of product dust within the packaging room and where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least six inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, should not be allowed in the packaging room.

§ 58.212 Hopper or dump room.

A separate room shall be provided for the transfer of bulk dry dairy products to the hoppers and conveyors which lead to the fillers. This room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities provided for the transfer of dry dairy products from portable bulk bins will be accepted if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

§ 58.213 Repackaging room.

A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

EQUIPMENT AND UTENSILS

§ 58.214 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of dry milk products, including pasteurizer, timing-pump or device, flow diversion valve and recorder controller, shall meet the same general requirements as outlined in section 58.128 of this Subpart. In addition, for certain other equipment the following requirements shall be met.

§ 58.215 Pre-heaters.

The pre-heaters shall be of stainless steel or other equally corrosion resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

§ 58.216 Hotwells.

The hotwells shall be enclosed or covered and should be equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell. If used for holding high heat products, they should also have recorders.

§ 58.217 Evaporators and/or vacuum pans.

Evaporators or vacuum pans or both, with open type condensers shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product. New or replacement units shall comply with the 3–A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. When enclosed type condensers are used, no special controls are needed to prevent water from entering the product. Water collected from the condensing of product (cow water) in this equipment may be utilized for prerinsing and cleaning solution make-up; provided it is equipped with proper controls that will automatically divert water with entrained solids to the waste water system. "Cow water" shall not be used for acidified or final equipment rinse.

§ 58.218 Surge tanks.

If surge tanks are used for hot milk, and temperatures of product including foam being held in the surge tank during processing, is not maintained at a minimum of 150° F, then two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

§ 58.219 High pressure pumps and lines.

High pressure lines may be cleaned-in-place and shall be of such construction that dead ends, valves and the high pressure pumps can be disassembled for hand cleaning. The high pressure pump shall comply with the 3–A Sanitary Standard for Homogenizers and Pumps of the Plunger Type.

§ 58.220 Drying Systems.

(a) *Spray dryers.* Spray dryers shall be of a continuous discharge type and

all product contact surfaces shall be of stainless steel or other equally corrosion resistant material. All joints and seams in the product contact surfaces shall be welded and ground smooth. All dryers shall be constructed so as to facilitate ease in cleaning and inspection. Sight glasses or ports of sufficient size shall be located at strategic positions. Dryers shall be equipped with suitable air intake filters. The filter system shall comply with the applicable requirements of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas fired dryers, precautions should be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust or dirt. New systems, replacement systems, or portions of systems replaced shall comply with the requirements of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems.

(b) *Roller dryers.* (1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rust. The knives shall be maintained in such condition so as not to cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, the drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. All air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system shall consist of filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. All dryer adjustments shall be made and the dryer operating normally before food grade product is collected from the dryer.

(c) *Other drying systems.* These systems shall be constructed following the applicable principles of the 3–A Accepted Practices for Milk and Milk Products Spray Drying Systems.

§ 58.221 Collectors and conveyors.

Collectors shall be made of stainless steel or equally noncorrosive material and should be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall be in good condition and the system shall be of such construction that all parts are accessible for cleaning and inspection. Conveyors shall be of stainless steel or equally corrosion resistant material and should be constructed to facilitate thorough cleaning and inspection.

§ 58.222 Dry dairy product cooling equipment.

Cooling equipment shall be provided with sufficient capacity to cool the product as specified in 58.240. A suitable dry air supply with an effective filtering system meeting the requirements of 58.-220(a) shall be provided where air cooling and conveying is used.

§ 58.223 Special treatment equipment.

Any special equipment (instantizers, hammer mills, etc.) used to treat dry milk products shall be of sanitary construction and all parts shall be accessible for cleaning and inspection. New or replacement instantizing systems shall comply with the 3–A Accepted Practices for Instantizing Systems for Dry Milk and Dry Milk Products.

§ 58.224 Sifters.

All newly installed sifters used for dry milk and dry milk products shall comply with the 3–A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the 3–A Standard for sifters.

§ 58.225 Clothing and shoe covers.

Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the dryer when it is necessary to enter the dryer to perform the cleaning operation.

§ 58.226 Portable and stationary bulk bins.

Bulk bins shall be constructed of stainless steel, aluminum or other equally corrosion resistant materials, free from cracks, seams and must have an interior surface that is relatively smooth and easily cleanable. All product contact surfaces shall be easily accessible for cleaning. The capacity of each portable and bulk bin shall be limited to permit proper operating procedures such as sampling and daily removal of all product to preclude commingling of different days production.

§ 58.227 Sampling device.

If automatic sampling devices are used, they shall be constructed in such a manner as to prevent contamination of the product, and all parts must be readily accessible for cleaning. The type of sampler and the sampling procedure shall be as approved by the Administrator.

§ 58.228 Dump hoppers, screens, mixers and conveyors.

The product contact surfaces of dump hoppers, screens, mixers and conveyors which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless or equally corrosion resistant material and designed to prevent contamination. All parts should be accessible for cleaning. The dump hoppers shall be of such height above floor level as to prevent foreign material or spilled product from entering the hopper.

§ 58.229 Filler and packaging equipment.

All filling and packaging equipment shall be of sanitary construction and all parts, including valves and filler heads accessible for cleaning. New or replacement equipment should comply with the 3A Sanitary Standards for equipment for Packaging Dry Milk and Dry Milk Products.

§ 58.230 Heavy duty vacuum cleaners.

Each plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. The vacuum cleaner shall be of a type that has a collector or disposable bag which will not recontaminate the atmosphere of the processing and packaging areas. Regular scheduling shall be established for its use in vacuuming applicable areas.

Quality Specifications for Raw Materials

§ 58.231 General.

All raw materials received at the drying plant shall meet the following quality specifications.

§ 58.232 Milk.

Raw milk shall meet the requirements as outlined in section 58.132 thru 58.138 and, unless processed within two hours after being received, it shall be cooled to and held at a temperature of 45° F. or lower until processed.

§ 58.233 Skim milk.

The skim milk shall be separated from whole milk meeting the requirements as outlined in section 58.132 thru 58.138, and unless processed immediately, it shall be cooled to and maintained at a temperature of 45° F. or lower from the time of separating until the time of processing.

§ 58.234 Buttermilk.

Buttermilk for drying shall be fresh, sweet, and from the churning of sweet cream butter, with or without the addition of harmless lactic culture. No neutralizing agent or chemical preservative may be added. Fluid buttermilk, unless cultured, shall be held at 45° F. or lower unless processed within 2 hours.

§ 58.235 Modified dry milk products.

Dry milk products to which approved neutralizing agents or chemicals have been added or constituents removed to alter their original characteristics for processing or usage shall come from products meeting the requirements of 58.232, 58.233, or 58.234. These products shall meet the applicable labeling requirements.

OPERATIONS AND OPERATING PROCEDURES

§ 58.236 Pasteurization and heat treatment.

All milk and buttermilk used in the manufacture of dry milk products and modified dry milk products shall be pasteurized at the plant where dried, except that acidified buttermilk containing 40 percent or more solids may be transported to another plant for drying without repasteurization. Provided the condensed product is handled according to sanitary conditions approved by the Administrator.

(a) Pasteurization. (1) All milk or skim milk to be used in the manufacture of nonfat dry milk shall be pasteurized prior to condensing at a minimum temperature of 161° F. for at least 15 seconds or its equivalent in bacterial destruction. Condensed milk products made from pasteurized milk may be transported to a drying plant, provided that it shall be effectively repasteurized at the drying plant, prior to drying, at no less than 166° F. for 15 seconds or its equivalent in bacterial destruction.

(2) All buttermilk shall be pasteurized prior to condensing at a temperature of 161° F. for 15 seconds or its equivalent in bacterial destruction.

(b) *Heat treatment.*

(1) *High-heat.* The finished product shall not exceed 1.5 mg. undenatured whey protein nitrogen per gram of nonfat dry milk as classified in the U.S. Standards for Grades of Nonfat Dry Milk (Spray Process).

(2) *Medium-heat.* The finished product shall show undenatured whey protein nitrogen between the levels of "high-heat" and "low-heat" (1.51 to 5.99 mg.).

(3) *Low-heat.* The finished product shall show not less than 6.0 undenatured whey protein nitrogen per gram of nonfat dry milk as classified in the U.S. Standards for Grades of Nonfat Dry Milk (Spray Process).

§ 58.237 Condensed surge supply.

Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold only the minimum amount of condensed product necessary for a uniform flow to the dryers. Such tanks holding product at temperatures below 150° F. shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

§ 58.238 Condensed storage tanks.

Excess production of condensed product over that which the dryer will take continuously from the pans should be bypassed through a cooler into a storage tank at 50° F. or lower and held at this temperature until used.

Product cut-off points shall be made at least every 24 hours and the tank completely emptied, washed, and sanitized before reuse.

§ 58.239 Drying.

Each dryer should be operated to produce the highest quality dry product consistent with the most efficient operation. The dry products shall be removed from the drying chamber continuously during the drying process.

§ 58.240 Cooling dry products.

Prior to packaging and immediately following removal from the drying chamber the dry product shall be cooled to a temperature not exceeding 110° F, however, if the product is to be held in a bulk bin the temperature should be reduced to approximately 90° F but shall be not more than 110° F.

§ 58.241 Packaging, repackaging and storage.

(a) *Containers.* Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be any clean, sound commercially accepted container or packaging material which will satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. In no instance will containers which have previously been used for nonfood items, or food items which would be deleterious to the dairy product be allowed to be used for the bulk handling of dairy products.

(b) *Filling.* Empty containers shall be protected at all times from possible contamination and containers which are to be lined shall not be prepared more than one hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary a mechanical shaker shall be provided; the tapping or pounding of containers should be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of residual product before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. All exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The room shall be kept free of dust accumulation, waste, cartons, liners, or other refuse. Conveyors, packaging and carton making equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials of any kind shall be permitted in the repackaging or hopper room. The inlet openings of all hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention shall be given to cleaning equipment where residues of the dry product may accumulate. A thorough clean-up including windows, doors, walls, light fixtures and ledges, should be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers, shall be properly identified and disposed of as animal feed.

(d) *Storage.* (1) *Product.* The packaged dry milk product shall be stored or so arranged in aisles, rows, or sections and lots at least 18 inches from any wall and in such a manner as to be orderly, easily accessible for inspection or for cleaning of the room. All bags and small containers of products shall be placed on pallets elevated from the floor. Product in small containers may be stored by methods preventing direct contact with the floor when the condition of the container is satisfactorily maintained. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* All supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. It is preferable that supplies be stored in an area separate from that used for storing the dry products. Supplies shall be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers, they shall be kept in an enclosed metal cabinet, bins or on shelving and if not enclosed shall be protected from powder, and dust or other contamination. The room should be vacuumed as often as necessary and kept clean and orderly.

§ 58.242 Product adulteration.

All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry product with another shall be considered as an adulteration of that product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, provided appliable labeling requirements are met.

§ 58.243 Checking quality.

All milk, milk products and dry milk products shall be subject to inspection and analysis by the dairy plant for quality and condition throughout each processing operation. Periodically samples of product and environmental material shall be tested for salmonella. Test results shall be negative when samples are tested for salmonella. Line samples should be taken periodically as an aid to quality control in addition to the regular routine analysis made on the finished products.

§ 58.244 Number of samples.

As many samples shall be taken from each dryer production lot as is necessary to assure proper composition and quality control. A sufficient number of representative samples from the lot shall be taken to assure compliance with the stated net weight on the container.

§ 58.245 Method of official sample analysis.

Samples shall be tested according to the applicable methods of laboratory analysis contained in DA Instruction

918–103, 918–109–1 and 918–109–3 as issued by the USDA, Agricultural Marketing Service, Dairy Division.

§ 58.246 Cleaning of dryers, collectors, conveyors, ducts, sifters and storage bins.

This equipment shall be cleaned as often as is necessary to maintain such equipment in a clean and sanitary condition. The kind of cleaning procedure either wet or dry and the frequency of cleaning shall be based upon observation of actual operating results and conditions.

§ 58.247 Insect and rodent control program.

In addition to any commercial pest control service, if one is utilized, a specially designated employee should be made responsible for the performance of a regularly scheduled insect and rodent control program as outlined in University of Wisconsin Extension Bulletin A2518 or subsequent revisions thereof, or one equivalent thereto.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.248 Nonfat dry milk.

Nonfat dry milk in commercial bulk containers bearing an official identification shall meet the requirements of U.S. Extra Grade or U.S. Standard Grade.

Regular nonfat dry milk in consumer size packages which bears an official identification shall meet the requirements of U.S. Extra Grade. In addition, the nonfat dry milk shall be sampled and tested in accordance with §§ 58.244 and 58.245.

§ 58.249 Instant nonfat dry milk.

(a) Only instant nonfat dry milk manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in Subpart A of this part which has been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA U.S. Extra Grade, processed and packed inspection shield.

(b) Instant nonfat dry milk shall meet the applicable standard for U.S. Extra Grade.

§ 58.250 Dry whole milk.

Dry whole milk in commercial bulk containers which bears an official identification shall meet the requirements for the U.S. Standards for Grades of Dry Whole Milk. Quality requirements for dry whole milk in consumer packages shall be for U.S. Extra Grade and shall be gas packed with an oxygen content of not more than 2.0 percent.

§ 58.251 Dry buttermilk.

The quality requirements for all dry buttermilk bearing official identification shall be in accordance with U.S. Standards for Grades of Dry Buttermilk. Dry cultured buttermilk shall meet the same requirements as listed above except that allowances shall be made for increased acidity due to the culture process.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING BUTTER AND RELATED PRODUCTS

DEFINITIONS

§ 58.305 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning.

(a) *Butter.* The food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, with or without additional coloring matter, and containing not less than 80 percent by weight of milkfat, all tolerances having been allowed for.

(b) *Butteroil.* The food product resulting from the removal of practically all of the moisture and solids-not-fat from butter. It contains not less than 99.6 percent fat, and not more than 0.3 percent moisture; and not more than 0.1 percent other butter constituents, of which the salt shall be not more than 0.05 percent.

(c) *Anhydrous milkfat.* The food product resulting from the removal of practically all of the moisture and the solids-not-fat from pasteurized cream. It contains not less than 99.8 percent fat, and not more than 0.15 percent moisture.

(d) *Frozen cream.* Sweet cream which has been pasteurized and frozen. It contains approximately 40 percent milkfat.

(e) *Plastic cream.* Sweet cream which has been pasteurized and contains approximately 80 percent milkfat.

(f) *Whipped butter.* Butter which has been stirred or whipped to incorporate air or inert gas, until its volume has been increased up to a range of from 50 to 100 percent. It contains not less than 80.0 percent fat by weight.

ROOMS AND COMPARTMENTS

§ 58.311 Coolers and freezers.

The coolers and freezers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from insects, rodents, and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

§ 58.312 Churn rooms.

Churn rooms in addition to proper construction and sanitation shall be so equipped that the air is kept free from objectionable odors and vapors and extreme temperatures by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

§ 58.313 Print and bulk packaging rooms.

Rooms used for packaging print or bulk butter and related products should, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold (not more than 15 colonies per plate during a 15 min. exposure), dust, or other air-borne contamination and maintain a reasonable room temperature in accordance with good commercial practices.

EQUIPMENT AND UTENSILS

§ 58.314 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of butter and related products shall meet the same general requirements as outlined in section 58.128. In addition for certain other equipment, the following requirements shall be met.

§ 58.315 Continuous churns.

All product contact surfaces of the churn and related equipment shall be of noncorrosive material. All non-metallic product contact surfaces shall comply with 3–A Standards for Plastic, Rubber, and Rubber-Like Materials. All product contact surfaces of the churn and related equipment shall be readily accessible for cleaning and inspection. Construction shall follow the applicable principles of the 3–A Sanitary Standards.

§ 58.316 Conventional churns.

Churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks, and in good repair. All gasket material shall be fat resistant, nontoxic and reasonably durable. Seals around the doors shall be tight.

§ 58.317 Bulk butter trucks, boats, texturizers, and packers.

Bulk butter trucks, boats, texturizers, and packers shall be constructed of aluminum, stainless steel, or equally corrosion resistant metal free from cracks, seams and must have a surface that is relatively smooth and easily cleanable. All non-metallic product surfaces shall comply with 3–A Standards for Plastic, Rubber, and Rubber-Like Material.

§ 58.318 Butter, frozen or plastic cream melting machines.

Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, free from cracks and of sanitary construction, and readily cleanable.

§ 58.319 Printing equipment.

All printing equipment shall be designed so as to adequately protect the product and be readily demountable for cleaning of product contact surfaces. All product contact surfaces shall be aluminum, stainless steel or equally corrosion resistant metal, or plastic, rubber and rubber like material which comply with 3–A standards, except that conveyors may be constructed of material which can be properly cleaned and maintained in a satisfactory manner.

§ 58.320 Brine tanks.

Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank should also be provided with a satisfactory drainage outlet.

§ 58.321 Cream storage tanks.

Cream storage tanks shall meet the requirements of section 58.128(d). Cream storage tanks for continuous churns should be equipped with effective temperature controls and recording devices.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.322 Cream.

Cream separated at an approved plant and used for the manufacture of butter shall have been derived from raw material meeting the requirements as listed under §§ 58.132 thru 58.138 of this subpart.

The inspection of farm-separated cream to be used for manufacturing or processing into dairy products under this part shall be based on organoleptic examination and quality control tests to determine suitability of cream at the time of delivery thereof at the receiving plant or substation.

(a) *Organoleptic examination.* Cream received at an approved receiving plant, or substation shall be identified as to the producer, seller, or shipper from whom received. Each can of cream in each shipment shall be examined for physical characteristics, off-taste and odors including those associated with developed acidity. The condition of the cream shall be wholesome and characteristic of normal cream. The organoleptic examination and segregation of the cream which is used in the manufacturing or processing into butter, shall be consistent with the applicable flavor classification of butter set forth in the U.S. Standards for Grades of Butter. Any cream having pronounced or offensive off-taste or odors, or which is in an abnormal condition (including, but not being limited to surface mold, foamy, yeasty, fruity, or containing extraneous matter), or which is otherwise unwholesome, shall be rejected to the producer, seller, or shipper and shall not be used in the processing or manufacturing of dairy products.

(b) *Sediment content classification.* (1) For the purpose of quality control and establishing a rejection level of cream to the producer, seller, or shipper, the following classifications of cream for sediment shall be applicable using USDA Sediment Chart (7 CFR 58.2726) as the basis for classification.

(i) Sediment (off-the-bottom method):

No. 1—USDA Sediment Standard (not to exceed) 0.50 mg.
No. 2—USDA Sediment Standard (not to exceed) 1.00 mg.
No. 3—USDA Sediment Standard (not to exceed) 2.50 mg.

(ii) Sediment (mixed-can method):

No. 1—USDA Sediment Standard (not to exceed) 0.20 mg.
No. 2—USDA Sediment Standard (not to exceed) 0.30 mg.
No. 3—USDA Sediment Standard (not to exceed) 1.00 mg.

(2) At least twice each month one can of cream from each producer, seller, or shipper of farm separated cream shall be selected at random and tested by using the "off-the-bottom" method or the "mixed-can" method in accordance with acceptable and approved procedures.

(3) As a supplement to the regular sediment testing procedure it is recommended that whole-can filtering facilities be utilized for each can of each shipment of cream from the producer for coarse sediment or extraneous matter and rejections be made in accordance with State or Federal Food and Drug Administration practices.

(c) *Acceptable cream.* Cream acceptable pursuant to the requirements of paragraph (a) of this section for organoleptic examination and complying with No. 1 or No. 2 for sediment content may be used in the processing or manufacturing of dairy products.

(d) *Probational cream.* Cream acceptable pursuant to the requirements of paragraph (a) of this section for organoleptic examination but classified No. 3 for sediment content may be accepted for processing in an approved plant for three successive deliveries. Thereafter each successive delivery shall be tested for sediment content prior to acceptance. If the sediment content is in excess of No. 2 such cream shall be rejected to the producer, seller, or shipper, and successive deliveries shall continue to be rejected until the sediment content is No. 2, or better. As soon as any shipment of cream is classified as probationary a representative of the plant, receiving plant, or substation should contact the producer, seller, or shipper involved in the production of probational cream and if necessary arrange to inspect the equipment, utensils, and facilities at the farm, receiving plant or substation and to offer constructive assistance for improvement in the quality of the cream.

(e) *Rejected cream.* (1) The cream from a producer, seller or shipper who has failed to improve the quality of his cream during the probationary period so as to meet the requirements of No. 2, or better, for sediment shall be rejected cream. Any further acceptance of cream from such a producer, seller, or shipper shall be on the basis of testing each shipment for sediment content, prior to acceptance to determine if the cream is No. 2, or better. If all cans of cream of the subsequent shipment meet No. 2, or better, such cream shall be classified as probational cream. When three successive shipments indicate cream of No. 2, or better, the cream may again be accepted, subject to regular periodic testing and quality control measures.

(2) If the initial new shipment fails to meet the requirements of No. 2 cream, or better, the plant shall not accept such cream until a representative of the plant again contacts the producer, seller, or shipper for the purpose of offering constructive assistance in correcting the unsatisfactory condition.

(f) *Field service.* A representative of the plant should arrange to promptly contact each producer, seller, or shipper involved in the production of probational or reject cream for the purpose of offering constructive assistance for the improvement in the quality of the cream. If necessary, he should arrange to inspect the equipment, utensils, and facilities at the farm, receiving plant, or substation. A representative of the plant should visit each producer, seller, or shipper as often as is practicable to assist in and encourage the production of high quality cream.

(g) *Records.* Accurate plant records listing the results of quality tests made on raw cream shall be maintained on cream from each producer, seller, or shipper. Each producer, seller, or shipper, shipping probational or rejected cream, shall be informed immediately of the results of such quality tests. Producers, sellers, or shippers, shipping No. 1 and No. 2 cream should receive such information at the time of regular remittances. Such records shall be available for examination by the inspector and kept on file for at least one year.

(h) *Alternate quality program.* When a processor has in operation an acceptable quality program, at the producer level, which is approved by the Administrator as being effective in obtaining results comparable to or higher than the quality program as outlined above for cream, then such a program may be accepted in lieu of the program herein prescribed.

§ 58.323 Whipped butter.

Whipped butter to be eligible for official certification with a U.S. Grade shield shall be graded prior to whipping and shall have originated from an approved plant. If made from cream in a continuous churning and whipping process, the quality of the cream used shall meet the requirements of cream for butter of comparable U.S. Grade.

§ 58.324 Butteroil.

To produce butteroil eligible for official certification, the butter used shall conform to the flavor requirements of U.S. Grade AA, U.S. Grade A, or U.S. Grade B, and shall have been manufactured in an approved plant.

§ 58.325 Anhydrous milkfat.

Made by a continuous separation process directly from milk or cream. To produce anhydrous milkfat eligible for official certification, the cream used shall be comparable to the flavor quality specified above for U.S. Grade AA or U.S. Grade A butter. Appearance should be fairly smooth and uniform in consistency. The cream shall be pasteurized in accordance with the procedure for cream for butter making (§ 58.334a).

§ 58.326 Plastic cream.

To produce plastic cream eligible for official certification, the quality of the

cream used shall meet the requirements of cream acceptable for the manufacture of U.S. Grade AA or U.S. Grade A butter.

§ 58.327 Frozen cream.

To produce frozen cream eligible for official certification, the quality of the cream used shall meet the requirements of cream acceptable for the manufacture of U.S. Grade AA or U.S. Grade A butter.

§ 58.328 Salt.

The salt shall be free-flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

§ 58.329 Color.

Coloring, when used shall be Annatto or any color which is approved by the U.S. Food and Drug Administration.

§ 58.330 Butter starter cultures.

Harmless bacterial cultures when used in the development of flavor components in butter and related products shall have a pleasing and desirable flavor and shall have the ability to transmit these qualities to the finished product.

§ 58.331 Starter distillate.

The refined flavor components when used to flavor butter and related products. It shall be of food grade quality, free of extraneous material and prepared in accordance with good commercial practice.

OPERATIONS AND OPERATING PROCEDURES

§ 58.332 Segregation of raw material.

The milk and cream received at the dairy plant shall meet the quality specifications as indicated under section 58.322. The milk and cream should be segregated by quality and processed separately in such a manner that the finished product will fully meet the requirements of a particular U.S. Grade or other specification, whichever is applicable.

§ 58.334 Pasteurization.

The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product or by procedures as set forth by the Administrator.

(a) *Cream for butter making.* The cream for butter making shall be pasteurized at a temperature of not less than 165° F. and held continuously in a vat at such temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum temperature of not less than 185° F. for not less than 15 seconds; or it shall be pasteurized by any other equivalent temperature and holding time which will assure adequate pasteurization. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping-quality characteristics.

Adequate pasteurization control shall be used and the diversion valve shall be set to divert at no less than 185° F. with a 15 second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching 5° F. higher than the minimum temperature during the holding time. Covers shall also be kept closed during the holding and cooling period.

(b) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in (a) above, except, that the temperature for the vat method shall be not less than 170° F. for not less than 30 minutes, or not less than 190° F. for not less than 15 seconds or by any other temperature and holding time which will assure adequate pasteurization and comparable keeping-quality characteristics.

§ 58.335 Quality control tests.

All milk, cream and related products are subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow samples as often as necessary to check the effectiveness of processing and manufacturing and as an aid in correcting deficiencies in processing and manufacturing. Routine analysis shall be made on raw materials and finished products to assure adequate microbiological, composition and chemical control.

§ 58.336 Frequency of sampling for quality control of cream, butter and related products.

(a) *Microbiological.* Samples shall be taken from churnings or batches and should be taken as often as is necessary to insure microbiological control.

(b) *Composition.* Sampling and testing for product composition shall be made on churns or batches as often as is necessary to insure adequate composition control. For in-plant control, the Kohman or modified Kohman test may be used.

(c) *Chemical.* (1) *Acid degree value.* This test should be made on churnings or batches from samples taken from the cream as often as is necessary to aid in the control of lipase activity.

(2) *Free fatty acid.* This test should be made on churnings or batches from samples taken from the butter as often as is necessary to aid in the control of lipase activity.

(d) *Other analysis.* Other chemical analysis or physical measurements shall be performed as often as is necessary to insure meeting grade standards and contract specifications.

(e) *Weight or volume control.* Representative samples of the packaged product should be checked using procedures prescribed by the Administrator during the packaging operation to assure compliance with the stated net weight or volume on the container.

(f) *Keeping quality and stability.* Samples from churnings shall be subjected to a seven day keeping quality test at a temperature of 72° F. to establish and maintain a satisfactory keeping quality history. Optionally 98° F. for 48 hours may be used, however, in case of a dispute, the results of the seven days at 72° F. will prevail.

§ 58.337 Official test methods.

(a) *Chemical.* Chemical analyses except where otherwise prescribed herein, shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, published by the Association of Official Analytical Chemists, The Official and Tentative Methods of the American Oil Chemists Society or any other methods giving equivalent results.

(b) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described or suggested in the latest edition of Standard Methods for the Examination of Dairy Products, published by the American Public Health Association.

§ 58.338 Composition and wholesomeness.

All ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and all other necessary precautions shall be taken to prevent contamination of products. All finished products shall comply with the requirements of the Federal Food, Drug and Cosmetic Act, as to composition and wholesomeness.

§ 58.339 Containers.

(a) Containers used for the packaging of butter and related products shall be commercially acceptable containers or packaging material that will satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tube containing two pounds or less, to protect the product from contamination during subsequent handling.

(b) *Liners and wrappers.* Supplies of parchment liners, wrappers and other packaging material shall be protected against dust, mold and other possible contamination.

Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt solution in a suitable container constructed of stainless steel or other equally non-corrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The liners shall be effectively treated with a solution consisting of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

Other liners such as polyethylene shall be treated or handled in such a manner as to prevent contamination of the liner prior to filling.

(c) *Filling bulk butter containers.* The lined butter containers shall be protected from possible contamination prior to filling. Use of parchment liners may be accomplished by alternately inverting one container over the other or stacking the lined boxes on their sides in a rack, until ready for use. When using polyethylene

liners the boxes should be lined immediately prior to use. When packing butter into the bulk containers, care shall be taken to fill the corners leaving as few holes or openings as possible. The surface of the butter as well as the covering liner shall be smoothed evenly over the top surface before closing and sealing the container. Containers should be stacked only as high as the firmness of the product will support weight, so as not to crush or distort the container.

§ 58.340 Printing and packaging.

Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions. Separate rooms equipped with automatic filling and packaging equipment should be provided. The outside cartons should be removed from bulk butter in a room outside of the printing operation but the parchment removal and cutting of the butter may be done in the print room.

§ 58.341 Repackaging.

When officially graded or inspected bulk product is to be repackaged into consumer type packages for official grade labeling or other official identification, a supervisor of packaging shall be required and the plant, equipment, facilities and personnel shall meet the same specifications as outlined in this part, including such markings or identification as may be required.

§ 58.342 General identification.

Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor or other assigned plant identification (manufacturer's lot number, churn number, etc.) and any other identification that may be required. Packages of plastic or frozen cream shall be marked with the percent of milkfat.

§ 58.343 Storage of finished product in coolers.

All products shall be kept under refrigeration at temperatures of 40° F. or lower after packaging and until ready for distribution or shipment. The products shall not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

§ 58.344 Storage of finished product in freezer.

(a) *Sharp freezers.* Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced in such a manner that air can freely circulate between and around the packages. The rooms shall be maintained at −10° F. or lower and shall be equipped to provide sufficient high velocity, air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(b) *Freezer storage.* The room shall be maintained at a temperature of 0° F. or lower. Adequate air circulation is desirable.

Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced in such a manner as to permit rapid freezing and repiled, if necessary, at a later time.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.345 Butter.

The quality requirements for butter shall be in accordance with the U.S. Standards for Grades of Butter for U.S. Grade AA, U.S. Grade A, or U.S. Grade B, respectively.

In addition, the butter is subject to the following specifications when sampled and tested in accordance with sections 58.336 and 58.337.

Proteolytic count, not more than 100 per gram; yeast and mold count, not more than 20 per gram; coliform count, not more than 10 per gram.

Optional except when required or requested: Copper content, not more than 0.3 ppm; iron content, not more than 1.0 ppm; enterococci, not more than 10 per gram.

§ 58.346 Whipped butter.

The flavor requirements as applicable for Whipped Butter shall be in accordance with the U.S. Standards for Grades of Butter, U.S. Grade AA, U.S. Grade A, or U.S. Grade B respectively.

In addition, the whipped butter is subject to the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337.

Proteolytic count, not more than 100 per gram; yeast and mold count, not more than 20 per gram; coliform count, not more than 10 per gram.

Optional except when required or requested: Copper content, not more than 0.3 ppm; iron content, not more than 1.0 ppm; enterococci, not more than 10 per gram.

§ 58.347 Butteroil or anhydrous milkfat.

The flavor shall be bland, free from rancid, oxidized or other objectionable flavors.

In addition, the finished products shall meet the following specifications when sampled and tested in accordance with sections 58.336 and 58.337.

Butteroil		Anhydrous milk fat
Not less than 99.6 percent.	Milkfat	Not less than 99.8 percent.
Not more than 0.3 percent.	Moisture	Not more than 0.15 percent.
Not more than 0.1 percent.	Other butter constituents including salt.	
Not more than 0.05 percent.	Salt	
Not more than 0.5 percent (calculated as oleic acid).	Free fatty acids	Not more than 0.3 percent (calculated as oleic acid).
Not more than 0.1 milli equivalents per kilogram of fat.	Peroxide value	Not more than 0.1 milli equivalents per kilogram of fat.
Not more than 0.10 ppm.	Copper content	Not more than 0.10 ppm.

§ 58.348 Plastic cream.

The flavor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree; aged, bitter, flat, smothered and storage; and cooked and feed flavors to a definite degree. It shall be free from rancid, oxidized or other objectionable flavors.

In addition, the finished product shall meet the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337.

Standard plate count, not more than 30,000 per gram; coliform count, not more than 10 per gram; yeast and mold, not more than 20 per gram;

Optional except when required or requested: copper content not more than 0.3 ppm; iron content not more than 1.0 ppm.

§ 58.349 Frozen cream.

The flavor shall be sweet, pleasing and desirable, but may possess the following flavors to a slight degree: aged, bitter, flat, smothered, storage; and cooked and feed flavors to a definite degree. It shall be free from rancid, oxidized or other objectionable flavors.

In addition, the product shall meet the following specifications when sampled and tested in accordance with sections 58.336 and 58.337. Samples for analysis should be taken prior to freezing of the product.

Standard plate count, not more than 30,000 per ml.; coliform count, not more than 10 per ml.; yeast and mold, not more than 20 per ml.

Optional except when required or requested: copper content, not more than 0.3 ppm; iron content not more than 1.0 ppm.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

DEFINITIONS

§ 58.405 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Cheese.* The fresh or matured product obtained by draining after coagulation of milk, cream, skimmed or partly skimmed milk or a combination of some or all of these products and including any cheese that conforms to the provisions of 21 CFR 19.500 up to 19.750, "Definitions and Standards of Identity for Cheese and Cheese Products," Food and Drug Administration.

(b) *Milkfat from whey.* The fat obtained from the separation of cheese whey.

ROOMS AND COMPARTMENTS

§ 58.406 Starter facility.

A separate starter room or properly designed starter tanks and satisfactory air movement techniques shall be provided for the propagation and handling of starter cultures. All necessary precaution shall be taken to prevent contamination of the facility, equipment and the air therein. A filtered air supply with a minimum average efficiency of 90% when tested in accordance with the ASHRAE Synthetic Dust Arrestance Test should be provided so as to obtain outward movement of air from the room to minimize contamination.

§ 58.407 Make room.

The rooms in which the cheese is manufactured shall be of adequate size, and the equipment adequately spaced to permit movement around the equipment for proper cleaning and satisfactory working conditions. Adequate filtered air ventilation should be provided. When applicable, the mold count should be not more than 15 colonies per plate during a 15 minute exposure.

§ 58.408 Brine room.

A brine room, when applicable, should be a separate room constructed so it can be readily cleanable. The brine room equipment shall be maintained in good repair and corrosion kept at a minimum.

§ 58.409 Drying room.

When applicable, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Temperature and humidity control facilities should be provided which will promote the development of a sound, dry surface of the cheese.

§ 58.410 Paraffining room.

When applicable for rind cheese, a separate room or compartment should be provided for pariffining and boxing the cheese. The room shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

§ 58.411 Rindless cheese wrapping area.

For rindless cheese a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to unsatisfactory packaging of the cheese.

§ 58.412 Coolers or curing rooms.

Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese, and minimize the undesirable growth of mold. Proper circulation of air shall be maintained at all times. The shelves shall be kept clean and dry. This does not preclude the maintenance of suitable conditions for the curing of mold and surface ripened varieties.

§ 58.413 Cutting and packaging rooms.

When small packages of cheese are cut and wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and for the cutting and wrapping operation. The rooms shall be well lighted, ventilated and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room. The waste materials and waste cheese shall be disposed of in an environmentally and/or sanitary approved manner.

EQUIPMENT AND UTENSILS

§ 58.414 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of cheese and related products shall meet the same general requirements as outlined in section 58.128. In addition, for certain other equipment the following requirements shall be met.

§ 58.415 Starter vats.

Bulk starter vats shall be of stainless steel or equally corrosion resistant metal and should be constructed according to the applicable 3–A Sanitary Standards. New or replacement vats shall be constructed according to the applicable 3–A Sanitary Standards. The vats shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls such as valves, indicating and/or recording thermometers.

§ 58.416 Cheese vats, tanks and drain tables.

The vats, tanks and drain tables used for making cheese should be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16 gauge stainless steel or other equally corrosion resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

The vat, tank and/or drain table shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to this equipment. If this equipment is provided with removable cloth covers, they shall be clean.

§ 58.417 Mechanical agitators.

The mechanical agitators shall be of sanitary construction. The carriages shall be of the enclosed type and all product contact surfaces, shields, shafts, and hubs shall be constructed of stainless steel or other equally corrosion resistant metal. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Materials and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

§ 58.418 Automatic cheese making equipment.

(a) *Automatic Curd Maker.* The automatic curd making system shall be constructed of stainless steel or of material approved in the 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Material. All areas shall be free from cracks and rough surfaces and constructed so that they can be easily cleaned.

(b) *Curd conveying systems.* The curd conveying system, conveying lines and cyclone separator shall be constructed of stainless steel or other equally corrosion resistant metal and in such manner that it can be satisfactorily cleaned. The system shall be of sufficient size to handle the volume of curd and be provided with filtered air of the quality satisfactory for the intended use. Air compressors or vacuum pumps shall not be located in the processing or packaging areas.

(c) *Automatic salter.* The automatic salter shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be constructed to equally distribute the salt throughout the curd. It shall be designed to accurately weigh the amount of salt added. The automatic salter shall be constructed so that it can be satisfactorily cleaned. The salting system shall provide for adequate absorption of the salt in the curd. Water and steam used to moisten the curd prior to salting shall be potable water or culinary steam.

(d) *Automatic curd filler.* The automatic curd filler shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be of sufficient size to handle the volume of curd and constructed and controlled so as to accurately weigh the amount of curd as it fills. The curd filler shall be constructed so that it can be satisfactorily cleaned.

(e) *Hoop and barrel washer.* The washer shall be constructed so that it can be satisfactorily cleaned. It shall also be equipped with temperature and pressure controls to insure satisfactorily cleaning of the hoops or barrels. It should be adequately vented to the outside.

§ 58.419 Curd mill and miscellaneous equipment.

Knives, hand rakes, shovels, scoops, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3–A Sanitary Standards for Plastic and Rubber-like Material. The product contact surfaces of the curd mill should be of stainless steel. All pieces of equipment shall be so constructed that they can be kept clean and free from rough or sharp edges which might scratch the equipment or remove metal particles. The wires in the curd knives shall be stainless steel, kept tight and replaced when necessary.

§ 58.420 Hoops, forms and followers.

The hoops, forms, and followers shall be constructed of stainless steel, heavy tinned steel or other approved materials. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

§ 58.421 Press.

The cheese press should be constructed of stainless steel and all joints welded and all surfaces, seams and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single service press cloths shall be used only once.

§ 58.422 Brine tank.

The brine tank shall be constructed of suitable non-toxic material and should be resistant to corrosion, pitting or flaking. The brine tank shall be operated so as to assure the brine is clean, well circulated, and of the proper strength and temperature for the variety of cheese being made.

§ 58.423 Cheese vacuumizing chamber.

The vacuum chamber shall be satisfactorily constructed and maintained so that the product is not contaminated with rust or flaking paint. An inner liner of stainless steel or other corrosion resistant material should be provided.

§ 58.424 Monorail.

The monorail shall be constructed so as to prevent foreign material from falling on the cheese or cheese containers.

§ 58.425 Conveyor for moving and draining block or barrel cheese.

The conveyor shall be constructed so that it will not contaminate the cheese and be easily cleaned. It shall be installed so that the press drippings will not cause an environmental problem.

§ 58.426 Rindless cheese wrapping equipment.

The equipment used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces. The equipment used to apply shrinkable wrapping material to rindless cheese shall operate to maintain the natural intended shape of the cheese in an acceptable manner, reasonably smooth surfaces on the cheese and tightly adhere the wrapper to the surface of the cheese.

§ 58.427 Paraffin tanks.

The metal tank should be adequate in size, have wood rather than metal racks to support the cheese, have heat controls and an indicating thermometer. The cheese wax shall be kept clean.

§ 58.428 Speciality equipment.

All product contact areas of speciality equipment shall be constructed of stainless steel or of material approved in the 3–A Sanitary Standards for Plastic and Rubber and Rubber-Like Material, and constructed following 3–A Sanitary Standards principles.

§ 58.429 Washing machine.

When used, the washing machine for cheese cloths and bandages shall be of commercial quality and size; or of sufficient size to handle the applicable load. It should be equipped with temperature and water level controls.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.430 Milk.

The milk shall be fresh, sweet, pleasing and desirable in flavor and shall meet the requirements as outlined under section 58.132 thru 58.138. The milk may be adjusted by separating part of the fat from the milk or by adding one or more of the following dairy products: Cream, skim milk, concentrated skim milk, nonfat dry milk, and water in a quantity sufficient to reconstitute any concentrated or dry milk used. Such dairy products shall have originated from raw milk meeting the same requirements as outlined under §§ 58.132 thru 58.138.

§ 58.431 Hydrogen peroxide.

The solution shall comply with the specification of the U.S. Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain added preservative. Application and usage shall be as specified in the "Definitions and Standards of Identity for Cheese and Cheese Products", Food and Drug Administration.

§ 58.432 Catalase.

The catalase preparation shall be a stable, buffered solution, neutral in pH, having a potency of not less than 100 Kell units per milliliter. The source of the catalase, its application and usage shall be as specified in the "Definitions and Standards of Identity for Cheese and Cheese Products," Food and Drug Administration.

§ 58.433 Cheese cultures.

Harmless microbial cultures used in the development of acid and flavor components in cheese shall have a pleasing and desirable taste and odor and shall have the ability to actively produce the desired results in the cheese during the manufacturing process.

§ 58.434 Calcium chloride.

Calcium chloride, when used, shall meet the requirements of the Food Chemical Codex.

§ 58.435 Color.

Coloring when used, shall be Annatto or any cheese or butter color which meet the requirements of the Food and Drug Administration.

§ 58.436 Rennet, pepsin, other milk clotting enzymes and flavor enzymes.

Enzyme preparations used in the manufacture of cheese shall be safe and suitable.

§ 58.437 Salt.

The salt shall be free-flowing, white refined sodium chloride and shall meet the requirements of the Food Chemical Codex.

OPERATIONS AND OPERATING PROCEDURES

§ 58.438 Cheese from pasteurized milk.

If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161° F. for not less than 15 seconds or by any other acceptable combination of temperature and time treatment approved by the Administrator. HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between the time of pasteurization and setting, it shall be cooled to 45° F. or lower until time of setting.

§ 58.439 Cheese from unpasteurized milk.

If the cheese is labeled as "heat treated", "unpasteurized," "raw milk", or "for manufacturing" the milk may be raw or heated at temperatures below pasteurization. Cheese made from unpasteurized milk shall be cured for a period of 60 days at a temperature not less than 35° F. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45° F. or lower until time of setting.

§ 58.440 Make schedule.

A uniform schedule should be established and followed as closely as possible for the various steps of setting, cutting, cooking, draining the whey and milling the curd, to promote a uniform quality of cheese.

§ 58.441 Records.

Starter and make records should be kept at least three months.

§ 58.442 Laboratory and quality control tests.

(a) *Chemical analyses.* (1) *Milkfat and moisture.* One sample shall be tested from each vat of the finished cheese to assure compliance with composition requirements.

(2) *Test method.* Chemical analysis shall be made in accordance with the methods described in Official Methods of Analysis of the Association of Official Analytical Chemists as specified in the appropriate standards of identity, the

latest edition of Standard Methods or by other methods giving equivalent results.

(b) *Weight or volume control.* Representative samples of the finished product shall be checked during the packaging operation to assure compliance with the stated net weight on the container of consumer size packages.

§ 58.443 Whey handling.

(a) Adequate sanitary facilities shall be provided for the handling of whey. If outside, necessary precautions shall be taken to minimize flies, insects and development of objectionable odors.

(b) Whey or whey products intended for human food shall at all times be handled in a sanitary manner in accordance with the procedures of this subpart as specified for handling milk and dairy products.

(c) Milkfat from whey should not be more than four days old when shipped.

§ 58.444 Packaging and repackaging.

Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be practically free from mold and bacterial contamination.

When officially graded bulk cheese is to be repackaged into consumer type packages with official grade labels or other official identification, a supervisor of packaging shall be required. If the repackaging is performed in a plant other than the one in which the cheese is manufactured and the product is officially identified, the plant, equipment, facilities and personnel shall meet the same requirements as outlined in this part.

§ 58.445 General identification.

Bulk cheese for cutting and the container for cheese for manufacturing shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number or name and address of manufacturer. Each consumer sized container shall meet the applicable regulations of the Food and Drug Administration.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.446 Quality requirements.

(a) *Cheddar cheese.* The quality requirements for Cheddar cheese shall be in accordance with the U.S. Standards for Grades of Cheddar Cheese.

(b) *Colby cheese.* The quality requirements for Colby cheese shall be in accordance with the U.S. Standards for Grades of Colby Cheese.

(c) *Monterey (Monterey Jack) cheese.* The quality requirements for Monterey (Monterey Jack) cheese shall be in accordance with the U.S. Standards for Grades of Monterey (Monterey Jack) Cheese.

(d) *Swiss cheese, Emmentaler cheese.* The quality requirements for Swiss cheese, Emmentaler cheese shall be in accordance with the U.S. Standards for Grades for Swiss Cheese, Emmentaler Cheese.

(e) *Bulk American cheese for manufacturing.* The quality requirements for bulk American cheese for manufacturing shall be in accordance with the U.S. Standards for Grades of Bulk American Cheese for Manufacturing.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING COTTAGE CHEESE

DEFINITIONS

§ 58.505 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Condensed skim.* Skim milk which has been condensed to approximately one-third the original volume in accordance with standard commercial practice.

(b) *Cottage cheese.* (1) *Cottage cheese dry curd.* The soft uncured cheese meeting the requirements of 21 CFR 19.525 Food and Drug Administration.

(2) *Cottage cheese.* The soft uncured cheese meeting the requirements of 21 CFR 19.530, Food and Drug Administration.

(3) *Lowfat Cottage cheese.* The soft uncured cheese meeting the requirements of 21 CFR 19.531, Food and Drug Administration.

(c) *Direct acidification.* The production of cottage cheese, without the use of bacterial starter cultures, through the use of approved food grade acids. This product shall be labeled according to the requirements of 21 CFR 19.530(d), Food and Drug Administration.

(d) *Cottage cheese with fruits, nuts, chives, or other vegetables.* Shall consist of cottage cheese to which has been added fruits, nuts, chives or other vegetables. The finished cheese shall comply with § 58.505(b).

(e) *Cream.* The milkfat portion of milk which rises to the surface of milk on standing or is separated from it by centrifugal force and contains not less than 18.0 percent of milkfat.

(f) *Creaming mixture.* The creaming mixture consists of cream or a mixture of cream with milk or skim milk or both. To adjust the solids content, nonfat dry milk or concentrated skim milk may be added but not to exceed 3.0 percent by weight of the creaming mixture. It may or may not contain a culture of harmless lactic acid and flavor producing bacteria, food grade acid, salt, and stabilizers with or without carriers. The creaming mixture in its final form may or may not be homogenized and shall conform to the provisions of 21 CFR 19.530(b), Food and Drug Administration.

ROOMS AND COMPARTMENTS

§ 58.510 Rooms and compartments.

(a) Processing operations with open cheese vats should be separated from other rooms or areas. Excessive personnel traffic or other possible contaminating conditions should be avoided. Rooms, compartments, coolers, and dry storage space in which any raw material, packaging or ingredients supplies or finished products are handled, processed, packaged or stored shall be designed and constructed to assure clean and orderly operations.

(b) *Ventilation.* Processing and packaging rooms or compartments shall be ventilated to maintain sanitary conditions, preclude the growth of mold and air borne bacterial contaminants, prevent undue condensation of water vapor and minimize or eliminate objectionable odors. To minimize air borne contamination in processing and packaging rooms a filtered air supply meeting the requirements of § 58.510(c) shall be provided. The incoming air shall exert an outward pressure so that the movement of air will be outward and prevent the movement of unfiltered air inward.

(c) *Starter facility.* A separate starter room or properly designed starter tanks and satisfactory air movement techniques shall be provided for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of the room, equipment and the air therein. A filtered air supply with a minimum average efficiency of 90% when tested in accordance with the ASHRAE Synthetic Dust Arrestance Test should be provided so as to obtain an outward movement of air from the room to minimize contamination.

(d) *Coolers.* Coolers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products. Coolers shall be kept clean, orderly and free from mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

EQUIPMENT AND UTENSILS

§ 58.511 General construction, repair and installation.

The equipment and utensils used for the manufacture and handling of cottage cheese shall be as specified in section 58.128. In addition for certain other equipment the following requirements shall be met.

§ 58.512 Cheese vats or tanks.

Cheese vats or tanks shall meet the requirements of § 58.416. When direct steam injection is used for heating the milk, the vat or tank may be of single shell construction. The steam shall be culinary steam.

Vats shall be equipped with valves to control the heating and cooling medium and a suitable sanitary outlet valve. Vats used for creaming curd should be equipped with a refrigerated cooling medium. A circulating pump for the heating and cooling medium is recommended.

§ 58.513 Agitators.

Mechanical agitators shall meet the requirements of § 58.417.

§ 58.514 Container fillers.

Shall comply with the 3–A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

§ 58.515 Mixers.

Only mixers shall be used which will mix the cheese carefully and keep shattering of the curd particles to a minimum. They shall be constructed in such a manner as to be readily cleanable. If shafts extend through the wall of the tank below the level of product, they shall be equipped with proper seals which are readily removable for cleaning and sanitizing. The mixer shall be enclosed or equipped with tight fitting covers.

§ 58.516 Starter vats.

Bulk starter vats shall meet the requirements of § 58.415.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.517 General.

Raw materials used for manufacturing cottage cheese shall meet the following quality specifications.

§ 58.518 Milk.

The selection of raw milk for cottage cheese shall be in accordance with §§ 58.132 thru 58.138.

§ 58.519 Dairy products.

(a) *Raw skim milk.* All raw skim milk obtained from a secondary source shall be separated from milk meeting the same quality requirements for milk as outlined in section 58.518 above. Skim milk after being pasteurized and separated shall be cooled to 45°F or lower unless the skim milk is to be set for cheese within two hours after pasteurizing. The skim milk should not be more than 48 hours old from the time the milk was received at the plant and the skim milk is set for cheese.

(b) *Nonfat dry milk.* Nonfat dry milk, when used, shall be obtained from milk meeting the same quality requirements as outlined in § 58.518 above. It shall be processed according to the requirements of this Subpart, and should meet the requirements of § 58.236(b)(3).

(c) *Condensed skim milk.* Condensed skim milk, if used, shall be prepared from raw milk or skim milk that meets the same quality requirements outlined above for raw milk or skim milk. It shall be cooled promptly after drawing from the vacuum pan or evaporator and shall have been pasteurized before concentrating or during the manufacture. The standard plate count of the concentrated milk shall not exceed 30,000 per ml. at time of use.

(d) *Cream.* Any cream used for preparing the dressing for creamed cottage cheese shall be separated from milk meeting at least the same quality requirements as the skim milk used for making the curd. The flavor of the cream shall be fresh and sweet. Cream obtained from a secondary source shall meet the same requirements. The creaming mixture prepared from this cream, after pasteurization, shall have a standard plate count of no more than 30,000 per ml.

§ 58.520 Nondairy ingredients.

(a) *Calcium chloride.* Calcium chloride, when used, shall be of food grade quality and free from extraneous material.

(b) *Salt.* Salt shall be free flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

(c) *Other ingredients.* Other ingredients such as fruits, nuts, chives or other vegetables used or blended with cottage cheese shall be reasonably free of bacteria so as not to appreciably increase the bacterial count of the finished product. The various ingredients in kind shall be consistent in size and color so as to produce the desired appearance and appeal of the finished product. The flavor of the ingredients used shall be natural and represent the intended flavor and intensity desired in the finished product. Such ingredients shall be clean, wholesome, of uniformly good quality, free from mold, rancid or decomposed particles. Vegetables used in cottage cheese may first be soaked for 15 to 20 minutes in a cold 25 to 50 ppm chlorine solution to appreciably reduce the bacterial population. After soaking, the vegetables shall be drained and used soon thereafter.

OPERATIONS AND OPERATING PROCEDURES

§ 58.521 Pasteurization and product flow.

(a) The skim milk used for the manufacture of cottage cheese shall be pasteurized not more than 24 hours prior to the time of setting by heating every particle of skim milk to a temperature of 161° F. for not less than 15 seconds or by any other combination of temperature and time giving equivalent results. All skim milk must be cooled promptly to setting temperature. If held more than two hours between pasteurization and time of setting, the skim milk shall be cooled and held at 45° F. or lower until set.

(b) Cream or cheese dressing shall be pasteurized at not less than 150° F. for not less than 30 minutes or at not less than 166° F. for not less than 15 seconds or by any other combination of temperature and time treatment giving equivalent results. Cream and cheese dressing shall be cooled promptly to 40° F. or lower after pasteurization to aid in further cooling of cottage cheese curd for improved keeping quality.

(c) Reconstituted nonfat dry milk for cottage cheese manufacture need not be re-pasteurized provided it is reconstituted within two hours prior to the time of setting using water which is free from viable pathogenic or otherwise harmful microorganisms as well as microorganisms which may cause spoilage of cottage cheese. Skim milk separated from pasteurized whole milk need not be re-pasteurized provided it is separated in equipment from which all traces of raw milk from previous operations have been removed by proper cleaning and sanitizing.

§ 58.522 Reconstituting nonfat dry milk.

Nonfat dry milk shall be reconstituted in a sanitary manner.

§ 58.523 Laboratory and quality control tests.

(a) Quality control tests shall be made on samples as often as necessary to determine the shelf-life and stability of the finished product. Routine analyses shall be made on raw materials and finished product to assure satisfactory composition, shelf-life and stability.

(b) *Frequency of sampling.* (1) *Microbiological.* Samples of raw milk for testing shall be taken as prescribed in section 58.135. Representative samples shall be taken of finished cottage cheese and from each lot or batch of product used as an ingredient. For keeping quality tests representative samples shall be taken of finished cottage cheese;

(2) *Chemical.* (i) *Milkfat and Moisture.* Representative samples shall be taken of cottage cheese; dry cottage cheese shall be tested for moisture only.

(ii) *pH.* Representative samples shall be taken of finished cottage cheese.

(c) *Test methods.* (1) *Microbiological.* Microbiological determinations shall be made for coliform, psychrotrophic and yeasts and molds. These tests shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products, published by the American Public Health Association.

(2) *Chemical.* Chemical analysis shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, published by the Association of Official Analytical Chemists, the latest edition of Standard Methods for the Examination of Dairy Products, or by other methods giving equivalent results.

§ 58.524 Packaging and general identification.

(a) *Containers.* Containers used for packaging cottage cheese shall be any commercially acceptable multiple use or single service container or packaging material which will satisfactorily protect the contents through the regular channels of trade without significant impairment of quality with respect to flavor, or contamination under normal conditions of handling. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing two pounds or less, to protect the product from contamination during subsequent handling.

(b) *Packaging.* The cheese shall be packaged in a sanitary manner and automatic filling and capping equipment shall be used on all small sizes. The containers shall be checked weighed during the filling operation to assure they are filled uniformly to not less than the

stated net weight on the container. Also care shall be taken that the cottage cheese be of uniform consistency at the time of packaging to assure legal composition in all packages.

(c) *General identification.* Bulk packages containing cottage cheese shall be adequately and legibly marked with the name of the product, net weight, name and address of the manufacturer, lot number, code or date of packaging and any other identification as may be required. Consumer size packaged products shall meet the applicable regulations of the Food and Drug Administration.

§ 58.525 Storage of finished product.

Cottage cheese after packaging shall be promptly stored at a temperature of 45° F. or lower to maintain quality and condition until loaded for distribution. During distribution and storage prior to sale the product should be maintained at a temperature of 45° F. or lower. The product shall not be exposed to foreign odors or conditions such as drippage or condensation that might cause package or product damage. Packaged cottage cheese shall not be placed directly on floors.

REQUIREMENTS FOR COTTAGE CHEESE BEARING USDA OFFICIAL IDENTIFICATION

§ 58.526 Official identification.

(a) Only cottage cheese manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in Subpart A of this part which has been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA Quality Approved Inspection Shield.

(b) *Nonfat dry milk.* Nonfat dry milk, when used in cottage cheese bearing official identification, shall meet the requirements for U.S. Extra Grade (Spray Process), at time of use, and should be of U.S. Low Heat Classification (not less than 6.0 mg. undenatured whey protein nitrogen per gram of nonfat dry milk). In addition, the nonfat dry milk shall have a direct microscopic count not exceeding 75 million per gram. The age of the nonfat dry milk shall be covered by a USDA grading certificate, evidencing compliance with quality requirements, dated not more than 6 months prior to use of the dry milk. In the interim between manufacture and use, the nonfat dry milk shall be stored in a clean, dry, vermin-free space. In any case, if the nonfat dry milk is more than 120 days old, at time of use, it shall be examined for flavor to make certain that it meets the requirements for U.S. Extra Grade.

§ 58.527 Physical requirements.

(a) *Flavor.* The cottage cheese shall possess a mild pleasing flavor, similar to fresh whole milk or light cream and may possess the delicate flavor and aroma of a good lactic starter. The product may possess to a slight degree a feed, acid, or salty flavor but shall be free from chalky, bitter, utensil, fruity, yeasty, or other objectionable flavors.

(b) *Body and texture.* The curd particles shall have a meaty texture, but sufficiently tender to permit proper absorption of cream or cheese dressing. The texture shall be smooth and velvety and shall not be mealy, crumbly, pasty, sticky, mushy, watery, rubbery or slimy or possess any other objectionable characteristics of body and texture. Small curd style (cut with ¼ inch knives) should have curd particles approximately ¼ inch or less in size. Large curd style (cut with knives over ¼ inch) should have curd particles approximately ⅜ inch or more in size.

(c) *Color and appearance.* The finished cottage cheese, creamed or plain curd, shall have an attractive natural color and appearance with curd particles of reasonably uniform size. The creamed cottage cheese shall be uniformly mixed with the cream or dressing properly absorbed or adhering to the curd so as to prevent excessive drainage.

§ 58.528 Microbiological requirements.

Compliance shall be based on 3 out of 5 consecutive samples taken at the time of packaging.

(a) *Coliform.* Not more than 10 per gram.

(b) *Psychrotrophic.* No more than 100 per gram.

(c) *Yeasts and molds.* Not more than 10 per gram.

§ 58.529 Chemical requirements.

(a) *Moisture.* See 58.505(b).

(b) *Milkfat.* See 58.505(b).

(c) *pH.* Not higher than 5.2.

(d) *Phosphatase.* Not more than 4 micrograms of phenol equivalent per gram of cheese.

§ 58.530 Keeping quality requirements.

Keeping quality samples taken from the packaging line shall be held at 45° F. for 10 days. At the end of the 10 day period the samples shall possess a satisfactory flavor and appearance, and shall be free from bitter, sour, fruity, or other objectionable tastes and odors. The surface shall not be discolored, translucent, slimy or show any other objectionable condition.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING FROZEN DESSERTS

DEFINITIONS

§ 58.605 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning as applied to frozen desserts meeting FDA requirements and briefly defined as follows:

(a) *Ice cream.* The product conforming to the requirements of section 20.2 "Definitions and Standards of Identity for Frozen Desserts," U.S. Food and Drug Administration (21 CFR 20.2).

(b) *Frozen custard.* The product conforming to the requirements of section 20.2 "Definitions and Standards of Identity for Frozen Desserts," U.S. Food and Drug Administration (21 CFR 20.2).

(c) *Ice milk.* The product conforming to the requirements of section 20.3 "Definitions and Standards of Identity for Frozen Desserts," U.S. Food and Drug Administration (21 CFR 20.3).

(d) *Sherbet.* The product conforming to the requirements of section 20.4 "Definitions and Standards of Identity for Frozen Desserts," U.S. Food and Drug Administration (21 CFR 20.4).

(e) *Mellorine.* The product conforming to the requirements of section 20.8 "Definitions and Standards of Identity for Frozen Desserts," U.S. Food and Drug Administration (21 CFR 20.8).

(f) *Overrun.* The trade expression used to reference the increase in volume of the frozen product over the volume of the mix. This increase in volume is due to air being whipped into the product during the freezing process. It is expressed as percent of the volume of the mix.

(g) *Mix.* The trade name for the combined and processed ingredients which after freezing become a frozen dessert.

ROOMS AND COMPARTMENTS

§ 58.619 Mix processing room.

The rooms used for combining mix ingredients and processing the mix shall meet the applicable requirements for rooms specified in section 58.126. The room shall be ventilated to remove moisture and prevent condensation from forming on walls and ceiling. The room shall be well lighted.

§ 58.620 Freezing and packaging rooms.

The rooms used for freezing and packaging frozen desserts shall be adequate in size to permit satisfactory air circulation and maintained in a clean and sanitary condition. The rooms shall be constructed in the same manner as prescribed above for mix rooms.

§ 58.621 Freezing tunnels.

Freezing tunnels for quick freezing at extremely low temperatures shall be designed and constructed as to insure ease in cleaning and satisfactory conditions of operation.

§ 58.622 Hardening and storage rooms.

Hardening and storage rooms for frozen desserts shall be constructed of satisfactory material for this purpose. The rooms shall be maintained in a clean and orderly manner. Adequate shelves, bins, or pallets shall be provided to keep the packages of finished products off the floor and to prevent damage to the containers. Sufficient refrigeration should be provided to insure adequate storage temperature (−10° or lower). Air shall be circulated to maintain uniform temperature throughout the rooms. A vestibule or double entry way should be provided to minimize heat shock of the frozen products.

EQUIPMENT AND UTENSILS

§ 58.623 Homogenizer.

Homogenizer shall comply with 3–A Sanitary Standards.

§ 58.624 Freezers.

Product contact surfaces of freezers used to lower the temperature of the liquid mix to a semi-frozen mass by a stirring action shall be constructed of a stainless steel or equally corrosion resistant metal and all parts easily accessible for cleaning and sanitizing. Batch and continuous freezers should comply with the applicable 3–A Standards.

§ 58.625 Fruit or syrup feeders.

Fruit or syrup feeders inject flavoring material into the semi-frozen product. Product contact surfaces shall be constructed of stainless steel or equally corrosion resistant metal and all pumps shall be in accordance to 3–A Sanitary Standards for dairy equipment. The feeder shall be constructed to enable complete disassembly for cleaning and sanitizing.

§ 58.626 Packaging equipment.

Packaging equipment designed to mechanically fill and close single service containers with frozen desserts shall be constructed so that all product contact surfaces shall be of stainless steel or equally corrosion-resistant metal. All product contact surfaces shall be easily accessible for cleaning. The design and operation of the machine shall in no way contaminate the container of the finished product placed therein. New or replacement equipment shall comply with the 3A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.627 Milk and dairy products.

To produce ice cream and related products the raw milk and cream shall meet the quality requirements as prescribed in section 58.132 through 58.138, except that only commingled milk and cream meeting the bacteriological requirements of No. 1 shall be used.

§ 58.628 Sweetening agents.

Sweetening agents shall be clean and wholesome and consist of one or more of the approved sweeteners listed in section 58.605.

§ 58.629 Flavoring agents.

Flavoring agents either natural or artificial shall be wholesome and free from undesirable flavors. They must impart the desired characteristic to the finished product. Flavoring agents shall be one or more of those approved in section 58.605.

§ 58.630 Stabilizers.

Stabilizers shall be clean and wholesome and consist of one or more of those approved in section 58.605.

§ 58.631 Emulsifiers.

Emulsifiers shall be clean and wholesome and consist of one or more of those approved in section 58.605.

§ 58.632 Acid.

Acids used in sherbet shall be wholesome and of food grade quality and consist of one or more of those approved in section 58.605.

§ 58.633 Color.

Coloring used for ice cream and related products shall be those certified by the U.S. Food and Drug Administration as safe for human consumption.

OPERATIONS AND OPERATING PROCEDURES

§ 58.634 Assembling and combining mix ingredients.

The assembling and combining of mix ingredients for processing shall be in accordance with clean and sanitary methods and shall be consistent with good commercial practices. All raw materials shall be subjected to inspection for quality and condition prior to being combined and processed into the finished mix. All necessary precautions shall be taken to prevent the contamination of any raw material or the finished mix with any foreign substance.

§ 58.635 Pasteurization of the mix.

Every particle of the mix, except added flavoring ingredients, shall be pasteurized at not less than 155° F. and held at that temperature for 30 minutes or for 175° F. for 25 seconds; or it may be pasteurized by any other equivalent temperature and holding time which will assure adequate pasteurization.

§ 58.636 Homogenization.

Homogenization of the pasteurized mix shall be accomplished to effectively reduce the size of the milkfat globules and evenly disperse them throughout the mix.

§ 58.637 Cooling the mix.

The mix shall be immediately cooled to a temperature of 45° F or lower, and stored at this temperature until further processing begins.

§ 58.638 Freezing the mix.

After the mix enters the freezer, it shall be frozen as rapidly as possible to assure the formation of minute crystals. Proper adjustment of rate of flow, refrigerant and air pressure controls shall be achieved to assure correct overrun and consistency of the product for packaging and further freezing.

§ 58.639 Addition of flavor.

The addition of flavoring ingredients to semi-frozen mix just prior to packaging shall be performed in a clean and sanitary manner. Care shall be taken to insure the flavor injection equipment has been properly cleaned and sanitized prior to use and that the flavor ingredients are of good quality and wholesome.

§ 58.640 Packaging.

The packaging of the semifrozen product shall be done by means which will in no way contaminate the container or the product. When single service containers and lids are used, they shall be of good construction and protect the finished product. Containers used for frozen products shall be stored and handled in a sanitary manner so as to protect them from dust and bacterial contamination.

§ 58.641 Hardening and storage.

Immediately after the semifrozen product is placed in its intended container it shall be placed in a hardening tunnel or hardening room to continue the freezing process. Rapid freezing to 0° to —15° F is desirable to produce a good textured product.

§ 58.642 Quality control tests.

All mix ingredients shall be subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow line samples as often as necessary to check the effectiveness of processing and sanitation and as an aid in correcting deficiencies. Routine analysis shall be made on raw materials and finished products to assure adequate composition, weight or volume control.

§ 58.643 Frequency of sampling.

(a) *Microbiological.* Representative samples shall be taken from each type of mix, and for the finished frozen product one sample from each flavor made.

(b) *Composition.* Representative samples shall be tested for fat and solids-not-fat on each type of mix manufactured. Spot checks shall be made on the finished products as often as is necessary to assure compliance with composition standards.

(c) *Weight or volume control.* Representative samples of the packaged products shall be checked during the packaging operation to assure compliance with the stated volume on the container as well as weight and overrun requirements.

§ 58.644 Test methods.

(a) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products.

(b) *Chemical.* Chemical analysis shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, the latest edition of Standard Methods, or by other methods giving equivalent results.

§ 58.645 General identification.

The various types of frozen desserts shall be packaged and labeled in accordance with the applicable regulations of the Food and Drug Administration.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.646 Official identification.

(a) Only ice cream and related products manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in Subpart A of this part which

have been officially inspected in process and found to be in compliance with these requirements may be identified with the official USDA Quality Approved Inspection Shield.

(b) Dairy products used in the manufacture of frozen desserts for which there are U.S. grades established (nonfat dry milk, whole milk, buttermilk and whey) shall be U.S. Extra Grade or better, and in the case of unsalted butter, shall be no lower than U.S. Grade A. Dairy products for which there are no USDA grade shall meet the applicable requirements of this part which permit such product to bear the USDA Quality Approved Inspection Shield.

§ 58.647 Composition requirements for ice cream.

See section 58.605(a).

§ 58.648 Microbiological requirements for ice cream.

The finished product shall contain not more than 50,000 bacteria per gram as determined by the standard plate count, and shall contain not more than 10 coliform organisms per gram for plain and not more than 20 coliform per gram in chocolate, fruit, nut or other flavors in in three out of five samples.

§ 58.649 Physical requirements for ice cream.

(a) *Flavor.* The flavor of the finished ice cream shall be pleasing and desirable, and characteristic of the fresh milk and cream and the particular flavoring used.

(b) *Body and texture.* The body shall be firm, have substance and readily melt to a creamy consistency when exposed to room temperatures; the texture shall be fine, smooth, and have the appearance of creaminess throughout.

(c) *Color.* The color shall be attractive, pleasing, uniform and characteristic of the flavor represented.

§ 58.650 Requirements for frozen custard.

The same requirements apply as for ice cream except plain frozen custard shall have a minimum egg yolk solids content of 1.4 percent, and 1.12 percent when fruits, nuts and other such ingredients are used for flavoring.

§ 58.651 Requirements for ice milk.

The requirements are the same as for ice cream except: (a) the minimum milk fat content shall be 2 percent by weight and the maximum milk fat content 7 percent by weight, (b) the total milk solids content shall be no less than 11 percent by weight, (c) the minimum total food solids weight per gallon shall be 1.3 pounds, (d) no reduction in the standards are permitted when fruits, nuts and other such ingredients are used for flavoring.

§ 58.652 Composition requirements for sherbet.

See section 58.605(d).

§ 58.653 Microbiological requirements for sherbet.

The finished product shall contain not more than 50,000 bacteria per gram as determined by the standard plate count and shall contain not more than 10 coliform organisms per gram in three out of five samples.

§ 58.654 Physical requirements for sherbet.

(a) *Flavor.* The flavor of the finished sherbet shall be pleasing and desirable and characteristic of the particular flavoring used and shall impart a sweet yet tart sensation.

(b) *Body and texture.* The body shall be firm, compact, somewhat chewy and readily melt to an even syrupy consistency at room temperatures; the texture shall be smooth but not as fine as in ice cream and shall be even throughout.

(c) *Color.* The color shall be attractive, pleasing, uniform and characteristic of the flavor represented.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS

DEFINITIONS

§ 58.705 Meaning of Words.

(a) *Pasteurized process cheese and related products.* Pasteurized process cheese and related products are the foods which conform to the applicable provisions of Part 19, Title 21, sections 19.750 to 19.790, "Definitions and Standards of Identity for Cheese and Cheese Products," Food and Drug Administration.

(b) *Blend set up.* The trade term for a particular group of vat lots of cheese selected to form a blend based upon their combined ability to impart the desired characteristics to a pasteurized process cheese product.

(c) *Cooker batch.* The amount of cheese and added optional ingredients placed into a cooker at one time, heated to pasteurization temperature, and held for the required length of time.

EQUIPMENT AND UTENSILS

§ 58.706 General construction repair and installation.

The equipment and utensils used for the handling and processing of cheese products shall be as specified in section 58.128 of this subpart. In addition, for certain other equipment the following requirements shall be met.

§ 58.707 Conveyors.

Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

§ 58.708 Grinders or shredders.

The grinders or shredders used in the preparation of the trimmed and cleaned cheese shall be of corrosion-resistant material, and of such construction as to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

§ 58.709 Cookers.

The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer, and shall be equipped with a temperature recording device. The recording thermometer stem may be placed in the cooker if satisfactory time charts are obtained, if not, the stem shall be placed in the hotwell or filler hopper. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product only culinary steam shall be used (see section 58.127(d)).

§ 58.710 Fillers.

A strainer should be installed between the cooker and the filler. The hoppers of all filters shall be covered but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side wall. The filler valves and head shall be kept in good repair and capable of accurate measurements. Product contact surfaces shall be of stainless steel or other corrosion resistant material.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

§ 58.711 Cheddar, colby, washed or soaked curd, granular or stirred curd cheese.

Cheese, used in the manufacture of pasteurized process cheese products should possess a pleasing and desirable taste and odor consistent with the age of the cheese; should have body and texture characteristics which will impart the desired body and texture characteristics in the finished product; and should possess finish and appearance characteristics which will permit removal of all packaging material and surface defects. The cheese should at least meet the requirements equivalent to U.S. Standard Grade for Bulk American Cheese for Manufacturing provided the quantity of the cheese with any one defect as listed for U.S. Standard Grade is limited to assure a satisfactory finished product.

§ 58.712 Swiss.

Swiss cheese used in the manufacture of pasteurized process cheese and related products should be equivalent to U.S. Grade B or better, except that the cheese may be blind or possess finish characteristics which do not impair the interior quality.

§ 58.713 Gruyere.

Gruyere cheese used in the manufacture of process cheese and related products should be of good wholesome quality

and except for smaller eyes and sharper flavor shall meet the same requirements as for Swiss cheese.

§ 58.714 Cream cheese, Neufchatel cheese.

These cheeses when mixed with other foods, or used for spreads and dips should possess a fresh, pleasing and desirable flavor.

§ 58.715 Cream, plastic cream and anhydrous milkfat.

These food products shall be pasteurized, sweet, have a pleasing and desirable flavor and be free from objectionable flavors, and shall be obtained from milk which complies with the quality requirements as specified in section 58.132 through 58.138 of this Subpart.

§ 58.716 Nonfat dry milk.

Nonfat dry milk used in cheese products should meet the requirements equivalent to U.S. Extra Grade except that the moisture content may be in excess of that specified for the particular grade.

§ 58.717 Whey.

Whey used in cheese products should meet the requirements equivalent to USDA Extra Grade except that the moisture requirement for dry whey may be waived.

§ 58.718 Flavor ingredients.

Flavor ingredients used in process cheese and related products shall be those permitted by the Food and Drug Standards of Identity, and in no way deleterious to the quality or flavor of the finished product. In the case of bulky flavoring ingredients such as pimento, the particles should be, to at least a reasonable degree, uniform in size, shape and consistency. The individual types of flavoring materials should be uniform in color and should impart the characteristic flavor desired in the finished product.

§ 58.719 Coloring.

Coloring shall be Annatto or any other cheese or butter color which is approved by the Food and Drug Administration.

§ 58.720 Acidifying agents.

Acidifying agents if used shall be those permitted by the Food and Drug Administration for the specific pasteurized process cheese product.

§ 58.721 Salt.

Salt shall be free flowing, white refined sodium chloride and shall meet the requirements of The Food Chemical Codex.

§ 58.722 Emulsifying agents.

Emulsifying agents shall be those permitted by the Food and Drug Administration for the specific pasteurized process cheese product, and shall be free from extraneous material.

OPERATIONS AND OPERATING PROCEDURES

§ 58.723 Basis for selecting cheese for processing.

A representative sample shall have been examined to determine fat and moisture content. One sample unit from each vat of cheese shall have been examined to determine the suitability of the vat for use in process cheese products in accordance with the flavor, body and texture characteristics permitted in sections 58.711 through 58.714 as applicable, and to determine the characteristics it will contribute to the finished product when blended with other cheese. The cheese included in each blend shall be selected on the basis of the desirable qualities which will result in the desired finished product. Recook from equivalent blends may be used in an amount that will not adversely affect the finished product. Hot cheese from the filler may be added to the cooker in amounts which will not adversely affect the finished product.

§ 58.724 Blending.

To as great an extent as is practical, each vat of cheese should be divided and distributed throughout numerous cooker batches. The purpose being to minimize the preponderance and consequent influence of any one vat on the characteristics of the finished product, and to promote as much uniformity as is practical. In blending also consider the final composition requirements for fat and moisture. Quantities of salt, color, emulsifier and other allowable ingredients to be added shall be calculated and predetermined for each cooker batch.

§ 58.725 Trimming and cleaning.

The natural cheese shall be cleaned free of all non-edible portions. Paraffin and bandages as well as rind surface, mold or unclean areas or any other part which is unwholesome or unappetizing shall be removed.

§ 58.726 Cutting and grinding.

The trimmed and cleaned cheese should be cut into sections of convenient size to be handled by the grinder or shredder. The grinding and mixing of the blended lots of cheese should be done in such a manner as to insure a homogeneous mixture throughout the batch.

§ 58.727 Adding optional ingredients.

As each batch is added to the cooker, the predetermined amounts of salt, emulsifiers, color, or other allowable optional ingredients shall be added. However, a special blending vat may be used to mix the ground cheese and other ingredients before they enter the cooker, to provide composition control.

§ 58.728 Cooking the batch.

Each batch of cheese within the cooker, including the optional ingredients, shall be thoroughly commingled and the contents pasteurized at a temperature of at least 158° F. and held at that temperature for not less than 30 seconds or any other equally effective combination of time and temperature approved by the Administrator. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

§ 58.729 Forming containers.

Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews should be done with extreme care and observance of personal cleanliness. Preforming and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

§ 58.730 Filling containers.

Hot fluid cheese from the cookers may be held in hotwells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or container in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

§ 58.731 Closing and sealing containers.

Pouches, liners, or containers having product contact surfaces, after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, so as to assure against contamination. Each container in addition to other required labeling shall be coded in such a manner as to be easily identified as to date of manufacture by lot or sublot number.

§ 58.732 Cooling the packaged cheese.

After the containers are filled they shall be stacked, or cased and stacked in such a manner as to prevent breaking of seals due to excessive bulging and to allow immediate progressive cooling of the individual containers of cheese. As a minimum the cheese should be cooled to a temperature of 100° F. or lower within 24 hours after filling. The temperature of the cheese should be reduced further, before being shipped or if storage is intended.

§ 58.733 Quality control tests.

(a) *Chemical analyses.* The following chemical analyses shall be performed in accordance with the appropriate edition of the Official Methods of Analysis of the AOAC as specified in the appropriate Standards of Identity or in accordance with methods that give equivalent results.

(1) *Cheese.* A representative sample of cheese used in the manufacture of pasteurized process cheese products shall have been tested prior to usage to determine its moisture and fat content.

(2) *Pasteurized process cheese products.* As many samples shall be taken of the finished product direct from the cooker, hopper, filler, or other location, as is necessary to assure compliance with composition requirements. Spot checks should be made on samples from the cooker as frequently as is necessary to

indicate pasteurization by means of the phosphatase test, as well as any other tests necessary to assure good quality control.

(b) *Examination of physical characteristics.* As many samples shall be taken as is necessary to assure meeting the required physical characteristics of the products. Representative samples shall be taken from production for examination of physical characteristics. The samples shall be examined at approximately 70° F. the first day of operation after the date of processing for the following characteristics. (1) Finish and appearance, (2) flavor, (3) color, (4) body and texture, and (5) slicing or spreading properties.

(c) *Keeping quality.* During processing or preferably from the cooled stock select sufficient samples at random from the production run. The samples should be stored at approximately 50° F. for 3 months for evaluation of physical characteristics as in (b) above. Additional samples may be selected and held at different temperatures or time.

(d) *Weight control.* During the filling operation as many samples shall be randomly selected and weighed from each production run as is necessary to assure accuracy of the net weight established for the finished products.

REQUIREMENTS FOR PROCESSED CHEESE PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.734 Official identification.

Only process cheese products manufactured and packaged in accordance with the requirements of this part and with the applicable requirements in Subpart A of this part which have been officially inspected in process and found to be in compliance with these requirements may be identified with official USDA Quality Approved Inspection Shield.

§ 58.735 Quality specifications for raw materials.

§ 58.735(a) Cheddar, colby, washed or soaked curd, granular or stirred curd cheese.

Cheese, used in the manufacture of pasteurized process cheese products which are identified with the USDA official identification shall possess a pleasing and desirable taste and odor consistent with the age of the cheese; shall have body and texture characteristics which will impart the desired body and texture characteristics in the finished product; and shall possess finish and appearance characteristics which will permit removal of all packaging material and surface defects. The cheese shall at least meet the requirements of U.S. Standard Grade for Bulk American Cheese for Manufacturing provided the quantity of the cheese with any one defect as listed for U.S. Standard Grade is limited, to assure compliance with the specifications of the finished product.

§ 58.735(b) Swiss.

Swiss cheese used in the manufacture of pasteurized process cheese and related products bearing official identification shall be U.S. Grade B or better, except that the cheese may be blind or possess finish characteristics which do not impair the interior quality.

§ 58.735(c) Gruyere.

Gruyere cheese used in the manufacture of process cheese and related products shall be of good wholesome quality and except for smaller eyes and sharper flavor shall meet the same requirements as for Swiss cheese.

§ 58.735(d) Cream cheese, Neufchatel cheese.

Mixed with other foods, or used for spreads and dips shall possess a fresh, pleasing and desirable flavor.

§ 58.735(e) Cream, plastic cream and anhydrous milkfat.

These food products shall be pasteurized, sweet, have a pleasing and desirable flavor and be free from objectionable flavors, and shall be obtained from milk which complies with the quality requirements as specified in section 58.132 of this Subpart.

§ 58.735(f) Nonfat dry milk.

Nonfat dry milk used in officially identified cheese products shall meet the requirements of U.S. Extra Grade except that the moisture content may be in excess of that specified for the particular grade.

§ 58.735(g) Whey.

Condensed or dry whey used in officially identified cheese products shall meet the requirements for USDA Extra Grade except that the moisture requirement for dry whey may be waived.

§ 58.735(h) Flavor ingredients.

Flavor ingredients used in process cheese and related products shall be those permitted by the Food and Drug Standards of Identity, and in no way deleterious to the quality or flavor of the finished product. In the case of bulky flavoring ingredients such as pimento, the particles shall be, to at least a reasonable degree, uniform in size, shape and consistency. The individual types of flavoring materials shall be uniform in color and shall impart the characteristic flavor desired in the finished product.

(i) *Other ingredients.* For coloring, acidifying agents, salt, and emulsifying agents see sections 58.719, 58.720, 58.721 and 58.722.

QUALITY SPECIFICATIONS FOR FINISHED PRODUCTS

§ 58.736 Pasteurized process cheese.

Shall conform to the provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese and Related Products, Food and Drug Administration. The average age of the cheese in the blend shall be such that the desired flavor, body and texture will be achieved in the finished product. The quality of pasteurized process cheese shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor.* Has a pleasing and desirable mild cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked or very slight acid or emulsifier flavor; is free from any undesirable tastes and odors.

(b) *Body and texture.* Shall have a medium-firm, smooth and velvety body free from uncooked cheese particles. Is resilient and not tough, brittle, short, weak, or sticky. It shall be free from pin holes or openings except those caused by trapped steam. The cheese shall slice freely, and shall not stick to the knife or break when cut into approximately ⅛ inch slices. If in sliced form, the slices shall separate readily.

(c) *Color.* May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color use the color designations as depicted by the National Cheese Institute standard color guide for cheese.

(d) *Finish and appearance.* The wrapper may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled.

§ 58.737 Pasteurized process cheese food.

Shall conform to the provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese Food and Related Products, Food and Drug Administration. The average age of the cheese in the blend shall be such that the desired flavor, body and texture will be achieved in the finished product. The quality of pasteurized process cheese food shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor.* Has a pleasing and desirable mild cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked or very slight acid or emulsifier flavors; is free from any undesirable tastes and odors.

(b) *Body and texture.* Shall have a reasonably medium-firm smooth and velvety body and free from uncooked cheese particles. Is resilient and not tough, brittle, short or sticky. It shall be free from pin holes or openings except those caused by trapped steam. The product shall slice freely with only a slight amount of sticking and shall not break when cut into approximately ⅛ inch slices. If in sliced form, the slices shall separate readily.

(c) *Color.* May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color use the color designations as depicted by the National Cheese Institute standard color guide for cheese.

(d) *Finish and appearance.* The wrapper may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled.

§ 58.738 Pasteurized process cheese spread and related products.

Shall conform to the applicable provisions of the Definitions and Standards of Identity for Pasteurized Process Cheese Spreads, Food and Drug Administration. The pH of pasteurized process cheese spreads shall not be below 4.0.

The quality of pasteurized process cheese spreads shall be determined on the basis of flavor, body and texture, color, and finish and appearance.

(a) *Flavor.* Has a pleasing and desirable cheese taste and odor characteristic of the variety or varieties of cheese ingredients used. If additional optional ingredients are used they shall be incorporated in accordance with good commercial practices and the flavor imparted shall be pleasing and desirable. May have a slight cooked, acid, or emulsifier flavor; is free from any undesirable tastes and odors.

(b) *Body and texture.* Shall have a smooth body free from uncooked cheese particles and when packaged shall form into a homogeneous plastic mass, and be free from pin holes or openings except those caused by trapped steam. Product made for slicing shall slice freely when cut into approximately ⅛ inch slices with only a slight amount of sticking. Product made for spreading shall be spreadable at approximately 70° F.

(c) *Color.* May be colored or uncolored but shall be uniform throughout. If colored it shall be bright and not be dull or faded. To promote uniformity and a common reference to describe color the color designations as depicted by the National Cheese Institute standard color guide for cheese may be used.

(d) *Finish and appearance.* Wrappers, if used, may be slightly wrinkled but shall envelop the cheese, adhere closely to the surface, and be completely sealed and not broken or soiled. Other containers made of suitable materials shall be completely filled, sealed and not broken or soiled.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING WHEY, WHEY PRODUCTS AND LACTOSE

DEFINITIONS

§ 58.805 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Whey.* That product defined by the regulations of the Food and Drug Administration.

(b) *Dry Whey.* That product resulting from drying fresh whey which has been pasteurized and to which nothing has been added for preservative purposes or altering the natural acidity. It contains all constituents, except moisture, in the same relative proportions as in the whey.

(c) *Dry Sweet Whey.* Dry whey not over 0.16 percent titratable acidity on a reconstituted basis.

(d) *Dry Whey ——% Titratable Acidity.* Dry whey over 0.16 percent, but below 0.35 percent titratable acidity on a reconstituted basis. The blank being filled with the actual acidity.

(e) *Dry Acid Whey.* Dry whey with 0.35 percent or higher titratable acidity on a reconstituted basis.

(f) *Modified Whey Products:*

(i) Partially demineralized whey,

(ii) Partially delactosed whey,

(iii) Demineralized whey, and

(iv) Whey protein concentrate-products defined by regulations of the Food and Drug Administration.

(g) *Lactose (milk sugar).* That food product defined by regulations of the Food and Drug Administration.

ROOMS AND COMPARTMENTS

§ 58.806 General.

Dry storage of product, packaging room for bulk product, and hopper or dump room shall meet the requirements of §§ 58.210 through 58.212 as applicable.

EQUIPMENT AND UTENSILS

§ 58.807 General construction, repair and installation.

All equipment and utensils necessary for the manufacture of whey, whey products and lactose shall meet the same general requirements for materials and construction as outlined in sections 58.128 and 58.215 through 58.230 as applicable, except for the following:

(a) *Modified Whey Products.* Equipment for whey fractionation, such as ultrafiltration, reverse osmosis, gel filtration, and electrodialysis shall be constructed in accordance with 3–A sanitary design principles, except where engineering requirements preclude strict adherence to such standards. Materials used for product contact surfaces shall meet applicable 3–A Sanitary Standards or Food and Drug Administration requirements. All equipment shall be of sanitary construction and readily cleanable.

(b) *Lactose.* Equipment used in the further processing of lactose following its separation from whey shall have smooth surfaces, be cleanable, free from cracks or crevices, readily accessible for inspection and shall be constructed of non-toxic material meeting applicable Food and Drug Administration requirements and under conditions of use shall be resistant to corrosion, pitting or flaking. [The use of stainless steel is optional].

QUALITY SPECIFICATIONS FOR RAW MATERIALS

§ 58.808 Whey.

Whey for processing shall be fresh and originate from the processing of products made from milk meeting the requirements as outlined in section 58.132 through 58.138. Only those ingredients approved by the Food and Drug Administration may be added to the whey for processing, except when restricted by this subpart. Whey products to which approved ingredients have been added or constituents removed to alter original characteristics for processing or usage shall be labeled to meet the applicable requirements.

OPERATIONS AND OPERATING PROCEDURES

§ 58.809 Pasteurization.

(a) All fluid whey used in the manufacture of dry whey, dry whey products, modified whey products, and lactose shall be pasteurized prior to condensing. When the condensing and drying operations for dry whey take place at the same plant, the pasteurization may be located at a different point in the operation provided it will protect the quality of the finished product and not adversely affect the processing procedure.

(b) Pasteurized products transported to another plant for final processing shall be repasteurized, except that condensed whey containing 40 percent or more solids may be transported to another plant for further processing into dry whey, dry whey products or lactose without repasteurization.

(c) If whey is transferred to another plant for further processing, or if during the processing procedure unpasteurized ingredients are added (except those necessary for lactose crystallization), or processing procedures permit contamination or bacterial growth, the whey shall be repasteurized as close to the final drying operations as possible.

§ 58.810 Temperature requirements.

(a) Unless processed within 2 hours, all whey or condensed whey, except acid type whey with a titratable acidity of 0.40 percent or above, or a pH of 4.6 or below, shall be cooled to 45° F or less, or heated to 145° F or higher. Other temperatures may be used when essential for the technology of the process, such as lactose crystallization and membrane whey separation processes, when the quality and wholesomeness of the product is not impaired.

(b) Recording thermometers shall be required and so located to assure that the cooling or heating requirements in paragraph (a) of this section are met.

§ 58.811 General.

The operating procedures as contained in §§ 58.237 through 58.244, 58.246, 58.247, and 58.443(a) (b) shall be followed as applicable.

§ 58.812 Methods of official sample analysis.

Samples shall be tested according to the applicable methods of laboratory analysis contained in DA Instruction 918–109–2 and 918–109–3 as issued by the USDA, Agricultural Marketing Service, Dairy Division.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.813 Dry Whey.

The quality requirements for dry whey shall be in accordance with the U.S. Standards for Dry Whey.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING EVAPORATED, AND CONDENSED MILK OR ULTRA PASTEURIZED PRODUCTS

DEFINITIONS

§ 58.905 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Evaporated milk.* The liquid food made by evaporating sweet milk to such point that it contains not less than 7.5 percent of milkfat and not less than 25.5 percent of the total milk solids. The finished product shall conform to the requirements of section 18.520 "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.520).

(b) *Concentrated milk, plain condensed milk.* The product which conforms to the standard of identity for evaporated milk except that it is not processed by heat to prevent spoilage. The container may be unsealed, and stabilizing ingredients are not used. The finished product shall conform to the requirements of section 18.525 "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.525).

(c) *Sweetened condensed milk.* The liquid or semi-liquid food made by evaporating a mixture of sweet milk and refined sugar (sucrose) or any combination of refined sugar (sucrose) and refined corn sugar (dextrose) to such point that the finished sweetened condensed milk contains not less than 28.0 percent of total milk solids and not less than 8.5 percent of milkfat. The quantity of sugar used is sufficient to prevent spoilage. The finished product shall conform to the requirements of section 18.530 or 18.535, respectively, "Definitions and Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.530 and 18.535).

(d) *Ultra-pasteurized.* The product shall have been thermally processed at or above 280° F. for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

EQUIPMENT AND UTENSILS

§ 58.912 General construction, repair and installation.

The equipment and utensils used for processing and packaging evaporated, condensed or ultra pasteurized dairy products shall be as specified in section 58.128. In addition for certain other equipment, the following requirements shall be met.

§ 58.913 Evaporators and vacuum pans.

All equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids should comply with the requirements of the 3–A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans.

§ 58.914 Fillers.

Both gravity and vacuum type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion-resistant material; except that, certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Nonmetallic product contact surfaces shall comply with the requirements for 3–A Sanitary Standards for Plastic, and Rubber and Rubber-Like Materials. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

§ 58.915 Batch or continuous in-container thermal processing equipment.

Shall comply with Title 21, Chapter 1, Subpart 128b—"Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers." The equipment shall be maintained in such a manner as to assure control of the length of time of processing, and to minimize the number of damaged containers.

§ 58.916 Homogenizer.

Homogenizers where applicable shall be used to reduce the size of the fat particles and to evenly disperse them in the product. Homogenizers shall comply with the applicable 3–A Sanitary Standards.

OPERATIONS AND OPERATING PROCEDURES

§ 58.917 General.

There are many operations and procedures used in the preparation of evaporated, condensed and ultra pasteurized dairy products that are similar, therefore, the following general requirements will apply when such operations or procedures are used.

§ 58.918 Standardization.

The standardization of the product to obtain a finished product of a given composition shall be accomplished by the addition or removal of milkfat, milk solids-not-fat and/or water. The ingredients added to accomplish the desired composition shall be of the same hygenic quality as the product being standardized.

§ 58.919 Pre-heat, pasteurization.

When pasteurization is intended or required by either the vat method, HTST method, or by the HHST method it shall be accomplished by systems and equipment meeting the requirements outlined in section 58.128. Pre-heat temperatures prior to ultra pasteurization will be those that have the most favorable effect on the finished product.

§ 58.920 Homogenization.

Where applicable concentrated products shall be homogenized for the purpose of dispersing the fat throughout the product. The temperature of the product at time of homogenization and the pressure at which homogenization is accomplished will be that which accomplishes the most desired results in the finished products.

§ 58.921 Concentration.

Concentrating by evaporation shall be accomplished with a minimum of chemical change in the product. The equipment and systems used shall in no way contaminate or adversely affect the desirability of the finished product.

§ 58.922 Thermal processing.

The destruction of living organisms shall be performed in one of the following methods. (a) The complete in-container method, by heating the container and contents to a range of 212° F. to 280° F. for a sufficient time; (b) by a continuous flow process at or above 280° F. for at least 2 seconds, then packaged aseptically; (c) the product is first processed according to methods as in (b), then packaged and given further heat treatment to complete the process.

§ 58.923 Filling containers.

(a) The filling of small containers with product shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product in any way. After filling, the container shall be hermetically sealed.

(b) Bulk containers for the product shall be suitable and adequate to protect the product in storage or transit. The bulk container (including bulk tankers) shall be cleaned and sanitized before filling, and filled and closed in a sanitary manner.

§ 58.924 Aseptic filling.

A previously ultra pasteurized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The contrainers prior to being filled shall be sterilized and maintained, in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

§ 58.925 Sweetened condensed.

After condensing, the sweetened condensed product should be cooled rapidly to about 85° F. to induce crystallization of the oversaturated lactose. When the desired crystallization is reached further cooling is resumed to 68°–70° F.

§ 58.926 Heat stability.

Prior to thermal processing of concentrated products and where stabilizers are allowed, tests should be made on the heat stability of the product to determine necessity for, and the amount of stabilizer needed. Based on the stability tests, safe and suitable stabilizers and emulsifiers may be added.

§ 58.927 Storage.

Finished products which are to be held more than 30 days should be stored at temperatures below 72° F. Precautions shall be taken to prevent freezing of the product.

§ 58.928 Quality control tests.

All dairy products and other ingredients shall be subject to inspection for quality and condition throughout each processing operation. Quality control tests shall be made on flow samples as often as is necessary to check the effectiveness of processing and manufacturing and as an aid in correcting deficiencies. Routine analyses shall be made on raw materials and finished products to assure adequate composition control. For each batch or production run a keeping quality test shall be made to determine product stability.

§ 58.929 Frequency of sampling for quality control.

(a) *Composition.* Sampling and testing for composition shall be made on batches of product as often as is necessary to control composition. On continuous production runs, enough samples shall be taken throughout the run to adequately assure composition requirements.

(b) *Other chemical analysis or physical analysis.* Such tests shall be performed as often as is necessary to assure compliance with standards, specifications or contract requirements.

(c) *Weight or volume control.* Representative samples of the packaged products shall be checked during the filling operation to assure compliance with the stated net weight or volume on the container.

(d) *Keeping quality and stability.* A minimum of one sample from each batch of product or one representative sample per hour from a continuous production run shall be taken. For continuous runs, samples shall be taken at the start, each hour, and at the end of the run. Samples should also be taken after resumption of processing following an interruption in continuous operation. Each sample shall be incubated at 90° F. to 100° F. for seven days.

§ 58.930 Official test methods.

(a) *Chemical.* Chemical analysis, except where otherwise prescribed herein, shall be made in accordance with the methods described in the latest edition of Official Methods of Analysis of the AOAC or by the latest edition of Standard Methods for the Examination of Dairy Products.

(b) *Microbiological.* Microbiological determinations shall be made in accordance with the methods described in the latest edition of Standard Methods for the Examination of Dairy Products.

§ 58.931 General identification.

Bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor, a lot number and coded date of manufacture. Consumer sized containers shall meet the applicable regulations of the Food and Drug Administration.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

§ 58.932 Milk.

The raw milk shall meet the requirements as outlined in sections 58.132 through 58.138. Unless processed within two hours after being received, it shall be cooled to, and held at a temperature of 45° F. or lower until processed.

§ 58.933 Stabilizers.

Shall be those permitted by the Food and Drug Administration's "Standards of Identity" as optional ingredients for specific products. Stabilizers shall be free from extraneous material, be of food grade quality and not be in violation of the Federal Food, Drug and Cosmetic Act.

§ 58.934 Sugars.

Any sugar used in the manufacture of sweetened condensed or sterilized milk products shall be refined, and of food grade quality.

§ 58.935 Chocolate and cocoa.

Such products used as flavor ingredients shall meet the requirements of the Food and Drug Administration, "Definitions and Standards of Identity for Cocoa Products."

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

§ 58.936 Milk.

To process and Package evaporated and condensed milk of ultra-pasteurized dairy products eligible for official identification with the USDA Quality Approved Inspection Shield the raw incoming milk shall meet the requirements as outlined in sections 58.132 through 58.136. Unless processed within two hours after being received, it shall be cooled to, and held at a temperature of 45° F. or lower until processed.

§ 58.937 Physical requirements for evaporated milk.

(a) *Flavor.* The product shall possess a sweet, pleasing and desirable flavor with not more than a definite cooked flavor. It shall be free from scorched, oxidized or other objectionable tastes and odors.

(b) *Body and texture.* The product shall be of uniform consistency and appearance. It shall be smooth and free from fat separation, lumps, clots, gel formation, coarse milk solids precipitate or sedimentation and extraneous material.

(c) *Color.* The color shall be of a natural white or light cream.

(d) *Degree of burn-on.* The interior walls of the container shall not show excessive burn-on of product (product fused to more than 75 percent of the inner surface of the can).

(e) *Keeping quality.* Samples incubated at 90–100° F shall show no sensory, chemical or microbiological deterioration after seven days.

§ 58.938 Physical requirements and microbiological limits for sweetened condensed milk.

(a) *Flavor.*—Shall be sweet, clean, and free from rancid, oxidized, scorched, fermented, stale or other objectionable tastes and odors.

(b) *Color.* Shall be white to light cream.

(c) *Texture.* Shall be smooth and uniform, free from lumps or coarse graininess. There shall not be sufficient settling of the lactose to cause a deposit on the bottom of the container.

(d) *Body.* Shall be sufficiently viscous so that the product upon being poured at room temperature piles up above the surface of that previously poured, but does not retain a definite form.

(e) *Microbiological limits.*

(1) Coliforms, less than 10 per gram; (2) yeasts, less than 5 per gram; (3) molds, less than 5 per gram; (4) total plate count, less than 1,000 per gram.

(f) *Keeping quality.* Samples incubated at 90–100° F shall show no physical evidence of deterioration after seven days.

(g) *Composition.* Shall meet the minimum requirements as set forth in the "Standards of Identity for Milk and Cream," Food and Drug Administration (21 CFR 18.530). In addition, the quantity of refined sugar used shall be sufficient to give a sugar-in-water ratio of not less than 61.5 percent.

(h) *Sediment.* The amount of sediment retained on a lintine disc after a sample composed of 225 grams of product dissolved in 500 ml. of 140° F. water has passed through it, shall not exceed 0.10 mg. as indicated by the USDA Sediment Standard for Milk and Milk Products, (7 CFR 58.2726).

The reporting and/or record-keeping requirements contained herein have been approved by the Bureau of the Budget in acordance with the Federal Reports Act of 1942.

Done at Washington, D.C. this 2nd day of October 1975, to become effective January 2, 1976.

DONALD E. WILKINSON,
Administrator.

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